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Life-Sustaining Technologies and the Elderly

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Foreword

In September 1984, OTA received requests from both the House and Senate Aging Committees to study the implications for their constituents of medical technologies that can sustain life in patients who are critically or terminally ill. Both Committee Chairmen, Senator John Heinz and Congressman Edward Roybal, expressed concern about elderly persons whose rights as patients and dignity as citizens are, or are feared to be, jeopardized—either by unwanted aggressive medical treatment or, conversely, by financial barriers to treatment.

The Senate Special Committee on Aging cited "new questions about the quality of life" that accompanies increased survival made possible by "current and emerging methods of life support." The Committee requested a "thorough review of the ethical dilemmas concerning life and death decisions that are faced by health care practitioners, elderly patients themselves, and concerned family members." OTA was asked to explore the special problems related to treatment decisions for older patients who are cognitively impaired and, thus, unable to make their own decisions, and to compare alternate methods for specifying in advance one's wishes regarding treatment. The Senate Committee also expressed interest in comparative reviews of the various institutional and noninstitutional settings in which life-sustaining technologies are used.

The House Select Committee on Aging identified as the key issues those related to "financial access" to life-sustaining technologies and the "right to choose." Of special interest were ways to ensure that elderly persons retain autonomy in treatment decisions, and the roles of families, providers, and government in supporting patient autonomy. Ethical issues related to the use of technologies that are currently available or anticipated were to be reviewed to advance understanding about care of the critically and terminally ill elderly. OTA was asked to assess the costs to patients, their families, and the public, and to lay the groundwork for policies about Medicare and Medicaid reimbursement of these technologies. Also of interest to the House Committee were the growing use of home care and issues related to quality of care, especially in the home.

In response, OTA has conducted a study of a wide range of topics, some of which have recently been receiving a great deal of scrutiny inside and outside the government. In order to derive information specific enough to guide possible congressional action and to be responsive to the requesting Committees, this examination of the issues is specifically tied to *particular* life-sustaining technologies and their use with patients who are *elderly*. At the same time, much of this information is applicable to life-sustaining technology in general and to citizens of all ages.

OTA has tried to provide a strong sense of the human dimension in this report. In addition to descriptions of what is theoretically possible and statistically documentable, much information is presented about the experience of individual patients and their families. The case examples, of which there are many, are true stories. While no case is "typical," every one expresses the potential benefits or the potential burdens of life-sustaining treatments. Each makes clear and poignant the needs of patients, their families, and caregivers who are faced with decisions about—or the consequences of decisions about—the use of life-sustaining technologies.

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Summary and Policy Options

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Chapter 1

Summary and Policy Options

INTRODUCTION

The dramatic advances in life-sustaining medical technologies during the past three decades have been accompanied by rapid expansion in their availability and use. As equipment and procedures have been refined and experience accumulated, the necessary personnel, facilities, and reimbursement have expanded, and the clinical criteria guiding use have been broadened. The types of patients who become candidates for life-sustaining treatments have changed, and their numbers have increased sharply. Many of these patients are *elderly*. As the population ages, as once "extraordinary" measures become commonplace, and as ever-more powerful technologies emerge, it becomes increasingly important to understand the problems as well as the potential associated with the use of these technologies and to devise policies that reflect this understanding.

Technologies that support or replace the functioning of a vital organ are capable of saving and sustaining life and, sometimes, capable of restoring health and independence. However, an individual's response to treatment can seldom be predicted with certainty; thus, it is never clear that a "life-sustaining" technology will sustain the life of a particular patient or, if it does, for how long. The quality of the life that is sustained may be even harder to predict. Patients and other interested parties may evaluate differently the benefits and burdens associated with treatment versus nontreatment and with one treatment versus another. An important factor that further complicates matters is that many patients with life-threatening conditions are not able to understand their treatment options or to express preferences regarding them.

Public discussion about the use of life-sustaining technologies, either for individual cases or health care policy, is relatively new, but newsworthy. At any one time, many thousands of elderly persons are receiving life-sustaining interventions. The vast majority of cases go unnoticed except by the patients, family members, and others directly involved in making and living with difficult treatment decisions. However, a few of these cases gain notoriety and public attention as it becomes apparent either that treatment was unwanted or futile or, conversely, that some new medical breakthrough or personal triumph over adversity has occurred. Under public scrutiny, these cases make clear the interdependence of private health care decisions and the public policies that determine whether treatment choices are legal, ethically acceptable, economically feasible, and fair.

The legal, ethical, and economic questions raised by decisions about the use of life-sustaining technologies have been studied by scholars and policymakers both inside and outside the government. The first major government publications addressing access to and decisions regarding the use of life-sustaining treatment were prepared in the early 1980s by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Related research has been performed or sponsored by the Office of the Surgeon General, the General Accounting Office (GAO), the Congressional Budget Office (CBO), the National Institutes of Health (NIH), and the Office of Technology Assessment (OTA). These studies demonstrate the lack of consensus regarding appropriate use of life-sustaining technologies and the lack of consensus even about appropriate procedures for making those decisions.

This assessment draws on the earlier studies, but it is different from them in two important respects. First, it is focused on *particular technologies*. The discussion goes beyond abstract considerations related to the care of the critically and terminally ill to identify specific problems and potential solutions related to selected technologies used to treat or manage life-threatening conditions. Second, this assessment is focused on a *specified age group, i.e., persons over age 65*, rather than on all potential patients. The major purpose is to provide an array of options for public policy that will support wiser clinical decisions about the use of these technologies. Toward this goal, the assessment presents information about topics as diverse as the cost of equipment, competing ethical principles, the experience of patients and their families, and the training of health care professionals. The assessment synthesizes available and new information, from a new perspective, and from this it develops a set of issues and related options for congressional review.

Selected Life-Sustaining Technologies

Life-sustaining technologies are drugs, medical devices, or procedures that can keep individuals alive who would otherwise die within a foreseeable, but usually uncertain, time period. While these technologies share some common ethical, legal, and health care delivery problems, each has unique characteristics that either raise special questions or suggest possible solutions. Five specific technologies used to treat or manage life-threatening conditions are the focus of this assessment:

1. **Cardiopulmonary resuscitation** (CPR) refers to a range of technologies that restore heartbeat and maintain blood flow and breathing following cardiac or respiratory arrest. Resuscitation procedures range from **basic life support**, which uses manual external cardiac massage and mouth-to-mouth ventilation, to **advanced life support**, which may include application of prescription drugs and sophisticated devices such as an electrical defibrillator, temporary cardiac pacemaker, and mechanical ventilator. Resuscitation has extremely wide potential application because it can be applied to virtually any person whose heart stops beating.
2. **Mechanical ventilation** is the use of a machine to induce alternating inflation and deflation of the lungs, to regulate the exchange of gases in the blood. The most common type of ventilator (or "respirator") delivers inspiratory gases directly into the patient's airway through tubing that connects the patient to the machine. The technology is used to sustain patients whose spontaneous breathing is inadequate or has stopped altogether due to acute or chronic diseases of the neuromuscular, neurologic, or pulmonary system, or due to anesthesia or trauma. This assessment is particularly concerned with mechanical ventilation that becomes **prolonged** or **chronic**.
3. **Renal dialysis** is an artificial method of maintaining the chemical balance of the blood when the kidneys have failed. The blood is cleansed of impurities, either by cycling the blood through a machine and back into the patient via catheters (**hemodialysis**), or by cycling dialyzing fluid into and out of the abdomen using the patient's peritoneal membrane as a filter (**peritoneal dialysis**). Dialysis is used for patients in acute renal failure and those with chronic **end-stage renal disease** (ESRD).
4. **Nutritional support and hydration** refers to artificial methods of providing nourishment and fluids. The two modes of delivery are **enteral** (or tube feeding), in which nutritional formulas are delivered via a tube into the digestive tract, and **parenteral** that includes all methods other than enteral but is primarily intravenous feeding in which nourishment is delivered via catheter into the bloodstream. **Total parenteral nutrition** (TPN) is an intravenous procedure that supplies sufficient nutrients to maintain a person's weight indefinitely. Tube feeding and TPN are used primarily for people who are unable to take sufficient amounts of food and fluids by mouth or who are unable to digest and absorb them adequately.
5. **Antibiotics** are a large set of drugs used to cure or control numerous bacterial, viral, and fungal infections, including minor ones. Different families of antibiotics have been developed for use in combatting different types of infections. Antibiotics may be administered topically, orally, intravenously, or intramuscularly, in discrete doses or continuously. All antibiotics are potentially life-sustaining. By "life-sustaining antibiotic therapy" OTA means not a particular drug or family of drugs but the use of any antibiotic against a life-threatening infection.

With the exception of antibiotics, none of the five technologies examined in this assessment can *cure* the underlying condition that precipitated its use. Thus, among patients who receive these interventions and survive, health status and functional capacity vary widely. While some patients regain adequate natural function of the affected organ, others become permanently dependent on the life-sustaining technology (and they may be simultaneously dependent on more than one life-sustaining technology). They may require continuing medical care and, often, other forms of assistance.

The life-sustaining technologies OTA has studied are only a few of many possibilities. They were selected to illustrate significant ranges across such dimensions as burden, cost, and risk. For example, antibiotic therapy administered intravenously is relatively painless and nonrestrictive, especially in comparison with mechanical ventilation, hemodialysis, and TPN. Mechanical ventilation frequently involves continuous, round-the-clock application, while hemodialysis is typically applied three times per week for 3 to 5 hours per treatment. Resuscitation is, ideally, applied only once. Costs and expenditures, which are related to frequency and duration of treatment, range from minor to catastrophic. Available reimbursement may be near total or minimal. The technology may bring risks of serious complications (e.g., renal failure associated with mechanical ventilation) or, provided proper procedures are followed (e.g., to prevent catheter-related infection for TPN), it may be generally safe. While invasiveness and high cost may tend to restrict use, low risk and low cost (or generous reimbursement) may lead to overuse. All these factors bear on clinical decisionmaking.

The five technologies examined in this assessment also illustrate the variety of settings and circumstances in which life-sustaining treatment can be administered. Most of these technologies are now technically possible and available not only in acute care hospitals and intensive care units (ICUs), but in nursing homes, patients' homes, and other community settings. While intubation for mechanical ventilation is usually done by highly trained professionals in an emergency room or ICU, some stabilized ventilator patients can manage in their own homes. Basic resuscitation techniques can be performed by trained bystanders wherever a cardiac arrest occurs, but advanced CPR requires emergency transfer to a hospital.

Focus on the Elderly Population

This assessment focuses on elderly persons who are already receiving or who might become candidates for life-sustaining medical technologies. For purposes of this assessment, **the elderly population is defined as all persons aged 65 and over. OTA recognizes and emphasizes, however, that defining the elderly population on the basis of any chronological age criterion tends to mask the heterogeneity of that population.** Sixty-five, or any chronological age, is a poor indicator of biological function, physiological reserve, cognitive ability, or health care needs. The use of age 65 is justified, however, by its prominence in available health and demographic statistics and its relevance to eligibility criteria in current Federal and State health care programs, especially Medicare. To minimize the loss of analytical and descriptive rigor from using a single age criterion, this assessment refers wherever possible to subgroups of the elderly population (e.g., 65 to 74, 85 and over).

While many important considerations in the use of life-sustaining technologies apply regardless of the patient's age, some factors distinguish the elderly as a special population. These include:

- Elderly people, as a group, are at greater risk of life-threatening illness than younger people.
- Because both the prevalence and severity of chronic conditions and their associated disabilities increase in old age, elderly persons who experience a life-threatening illness are more likely than younger persons to already be in a state of compromised health and reduced functioning that negatively affects their quality of life.
- Elderly people are more likely than younger adults to be victims of a dementing illness, and they have high rates of other disorders (e.g., depression, drug toxicity) that may temporarily or permanently impair their ability to make health care decisions.
- Comorbidity (the coexistence of more than one disease) and age-associated loss of function complicate the prognosis and treatment

of life-threatening conditions in elderly persons.

- There are questions about the quality of health care currently available to elderly patients. Many health professionals in practice today are poorly prepared to care for seriously ill elderly people whose presentation of disease and response to treatment may differ from that of younger adults.
- As a group, elderly people utilize a large share of all health care resources and consume the largest share of public health care dollars.
- Elderly people, as the major beneficiaries of Medicare, may bear the brunt of Federal efforts to contain health care costs.
- In contrast to other segments of the population, especially newborns and young children, the law recognizes the autonomy of elderly adults.
- Elderly persons are more likely than younger adults to have contemplated the meaning and value of their life and its end.

The significance of the above factors will be heightened as the elderly population increases in absolute and relative size, and in average age. Demographers predict continuing growth of the elderly population, from approximately 25.5 million people and 11 percent of the U.S. population in 1980 to 35 million and 13 percent in 2000. Moreover, conservative projections indicate that the population aged 75 to 84, which accounted for 30 percent of the total elderly population in 1980, will reach 35 percent in 2000. During the same period, the proportion of persons 85 and older will increase from 9 to 15 percent of the population over 65.

Who Are the Life-Threatened Elderly?

In order to emphasize the diversity of the population at risk and to illuminate problems in making decisions about their care, OTA has devised a classification system consisting of four categories of "physical status" and four categories of "decisionmaking capacity." Most of these categories are not articulated in practice, but they influence a person's ability to make treatment decisions for himself or herself and may also influence the decisions that are made by others on a person's behalf.

Variation in Physical Status

A life-threatening condition may be—and in elderly persons frequently is—superimposed on preexisting physical and/or mental disorders, or it may occur in an otherwise healthy and active individual. **It is inappropriate for clinical decisionmakers or public policymakers to lump together all elderly persons who become candidates for life-sustaining technologies. Rather, the life-threatened elderly should be seen as individuals with widely varying physical and mental status.** Physical conditions may be acute or chronic, have different prognoses (both of survival and restoration of functional ability), and have a course that is either decisive or unknown.

1. **Critically ill** persons are those in the midst of an acute life-threatening episode (e.g., cardiac arrest, stroke) or persons believed to be in imminent danger of such an episode. They are medically unstable, and if they are not treated, are expected to decline.
2. **Chronically ill** persons have one or more chronic conditions that may or may not be life-threatening but that reduce chances of recovery and restoration of function in the event of an acute disease. Included in this group are persons who have a life-threatening chronic condition that has been stabilized, with or without a life-sustaining technology, or that is in remission (e.g., chronic renal failure treated with dialysis; cancer in remission). Many chronic conditions that are not immediately life-threatening are mildly or severely debilitating; some (e.g., hypertension) increase the risk of acute life-threatening illnesses or the risk of complications associated with acute disease.
3. **Severely debilitated** persons have serious or multiple impairments or comorbidities. Their functional capacity and physiological reserve are severely compromised. They are medically stable but highly vulnerable to new physiological stresses (e.g., at heightened risk of infections, iatrogenic illness, complications of treatment, and accidents).

4. **Terminally ill** individuals are those for whom a prognosis of death has been made. Designation as terminally ill usually requires diagnosis of an illness that has a predictably fatal progression that cannot be stopped by any known treatment.

A widely accepted definition of "terminal illness" includes the expectation that death will occur within 6 months. This definition has been adopted by Medicare. In practice, however, accurate prognosis is extremely difficult, and this difficulty adds to the dilemmas regarding treatment decisions. Contrary to popular belief, a terminal illness is not always identifiable as such, and most patients who are *dying* have not been declared "terminally ill." Only retrospectively can these designations be reliably made.

Variation in Decisionmaking Capacity

Cognitive ability has two elements of special importance in the context of this assessment. First, a person may be cognitively normal and fully capable of making decisions, severely cognitively impaired and completely incapable of making decisions, or somewhere in between; thus, there are differences in the *boundaries* or *content* of cognition. A person who is confused or disoriented to time and place, or even judged by a court to be incompetent,[1] may still be capable of making and expressing preferences regarding his or her medical treatment. It is this relatively narrow conception of cognitive ability, i.e., **decisionmaking capacity with respect to medical treatment**, that is central to this report. A second important element of cognitive ability is *temporal*. Like physical status, cognitive ability may be stable or fluctuating, and a person's decisionmaking capacity may be expected to improve or worsen. These distinctions result in four theoretical categories of patients, as follows:

1. Individuals may be **capable of making decisions** about their medical care (and all other aspects of their life), and their decisionmaking capacity may be assumed to be *stable*.
2. Individuals may be **currently capable** of making decisions about their medical care, but this status is assumed to be unstable or declining. Persons whose lucidity fluctuates and those with progressive dementing disorders are examples.
3. Individuals may be **currently incapable** of making decisions, but it is expected that their decisionmaking capacity will be restored. This category includes patients who are unconscious, severely depressed or confused due to *reversible* causes (e.g., anesthesia, drug toxicity, pain).
4. Individuals may be **permanently incapable** of making decisions about their medical care (and everything else). In these persons, there is no sign of ability to absorb and evaluate information or to express a preference, and there is no realistic prospect of change. Examples include patients in a persistent noncognitive state, irreversible coma, and persons who are severely demented.

Combining the physical status categories with the decisionmaking capacity categories produces a paradigm of 16 patient groups. However, an individual's placement in this scheme is subject to change (see fig. 1-1). This complexity accounts, in part, for the problems inherent in generalizations about the use of life-sustaining technologies.

The combination of a patient's physical and mental status may affect both the decisionmaking process and the decision that is reached. For example, in some States, a patient's request for nontreatment is granted only if the patient is deemed *both* decisionally capable and terminally ill. Or, a critically ill patient, regardless of decisionmaking capacity, might be excluded from the decisionmaking process because of the need for immediate action.

Accurate evaluation of decisionmaking capacity is critical, but problematic. Assessment procedures are not reliable and not necessarily comparable as applied in different institutions. Assessment of cognitive status may be particularly difficult when the patient's physical status is reduced by illness, drugs, or other medical interventions, or when the patient is depressed. Patients whose ability to communicate is impaired or unstable present added problems for accurate assessment.

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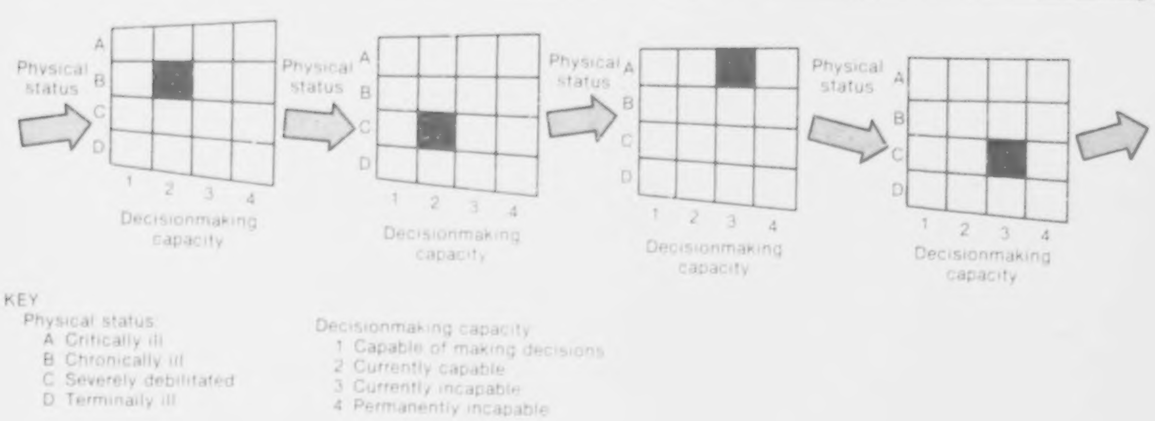
[1] In this assessment, OTA uses the term "incompetent" specifically to designate an assessment of cognitive ability that has been declared by a legal procedure.

Figure 1-1.—Heterogeneity of the Life-Threatened Elderly


Time
Physical status
A
B
C
D
1
2
3
4
Decisionmaking capacity
KEY
Physical status:
A Critically ill
B Chronically ill
C Severely debilitated
D Terminally ill
Decisionmaking capacity:
1 Capable of making decisions
2 Currently capable
3 Currently incapable
4 Permanently incapable

BACKGROUND

The findings presented in this chapter should be understood in relation to the various social phenomena that made an assessment of life-sustaining technologies timely in the first place. The historical context of this study is a stressful one, in which many things are changing rapidly and dramatically. The speed of technological advance is *unprecedented*, the elderly population is growing *geometrically*, health care is being *transformed*. The words and concepts that are part of this scenario—quality of life, autonomy, euthanasia, suicide, rationing, doctor-patient relationship, malpractice, old age—evoke strong, often conflicting, responses. Other important concepts are distinguished by their unfamiliarity: advance directive, living will, durable power of attorney, surrogate decisionmaker, prospective payment system, brain death. In this fluid environment, lags are inevitable: between new knowledge and its adoption, between technical capability and decisionmaking guidelines, between medical practice and legal protections.

In other parts of this report (especially chs. 2, 3, and 4), many of these concepts and trends are discussed in depth. They arise in the context of patients' legal rights and ways to exercise them; the cost of health care and efforts to contain them; how medical technologies are developed and accepted into practice; ethical bases for allocating health care resources; ethical and legal issues concerning the withholding and withdrawal[2] of treatments that sustain life; increased presence of the law and economics in medical practice; attitudes about illness, death, and dying; growth of the elderly population; and the emergence of geriatrics as a specialty within medicine, nursing, and other health professions. The background information presented in this chapter only suggests the range and importance of the social issues that drive concern about life-sustaining technologies.

The Specter of Rationing

The looming national debt and efforts to reduce it draw public attention to and impose new constraints on older questions about the allocation of public resources in general and health care resources in particular. At the global level, the total resource pool must be divided among all competing national interests, i.e., health, defense, education, foreign aid, the environment, crime, and so on. At the next level, health care resources (including financial, human, and technological resources) must be allocated among a myriad of potential beneficiaries and causes. Here the competition is between prevention and cure, acute care and long-term care, research and services, etc. Finally, at the micro-allocation level, specific health care resources must be distributed among the individuals who claim them. If there are 3 beds in an ICU and 4 patients, or 10 donor kidneys and 20 patients awaiting transplantation, difficult decisions must be made. At every level, our current fiscal consciousness intensifies the need to make wise choices—and to be able to demonstrate the benefits.

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[2] In this assessment, "withholding" is a decision to not initiate a life-sustaining intervention for a particular patient. Withholding may be the enactment of the patient's express wishes or the judgment of other persons that the application of medical technology is not warranted. "Withdrawal" means the discontinuance or removal of a life-sustaining intervention that has been initiated.

Many people see the present economic climate as a harbinger of inevitable rationing of scarce resources. In some circles, there is discussion of explicit criteria for allocating resources based, for example, on age, prognosis, or cost. Elsewhere, rationing is rejected outright as unnecessary and/or evil. Other solutions can be found, it is argued, if priorities are adjusted at the global level and demand for health care resources is modified (e.g., by improving disease prevention and eliminating the use of unnecessary medical procedures). Whether one favors or abhors health care rationing—or believes it is already here—the strong reaction this concept evokes is one of the major reasons for concern about high-technology health care.

The "High Cost of Dying"

Considerable attention has been drawn to the high cost of health care for the elderly population (in 1984, annual personal health care expenditures for Americans over 65 were projected at $120 billion, almost half of which would be paid by Medicare) and, in particular, to high Medicare expenditures for patients in the last year of life. The latter has been interpreted and widely referred to as the "high cost of dying." The implication has been that a great deal of money, in fact "too much" money, is spent on patients who are elderly, and too much of this on patients who *die anyway*. These figures have captured considerable attention and led many people to ask whether the benefits justify the cost. Further, because it is widely assumed that life-sustaining technologies are a major factor in the cost of care for persons who die, the value of this kind of treatment is often questioned. Projected increases in the elderly population and the increased costs these portend intensify the debate about what level of care is to be provided at public expense.

Concern about the "high cost of dying" persists despite recent analyses that put this cost in a different perspective. First, understandably, the cost of care is highest for people who get the most care, that is, those who are the sickest. Thus, what some decry as the high cost of dying others recognize as simply the cost of health care for very sick people, some of whom live, some of whom die, and many of whom are elderly. Equally important, analyses of Medicare expenditures show that the majority of elderly people who die do not incur high Medicare costs in their final year. And, of those elderly patients whose health care costs are very high, while approximately half die, the other half survive. Analysis of Medicare expenditures over the past 20 years also shows that the rate of increase has been about the same for patients who survive as for those who die, suggesting that the increase in expenditures is not due to disproportionate use of expensive life-sustaining technologies for those who die.

In 1983, to contain high Medicare expenditures, Congress mandated a new basis for payment of inpatient hospital claims. Under Medicare's Part A prospective payment system (PPS), payment for inpatient hospital care is based on predetermined amounts for patients in given diagnostic categories. Hospitals thus may show profit or loss, depending on their ability to keep their costs within the established payment limits. Hospitals and the physicians they employ now have strong economic incentives to be more selective in the type, amount, or duration of treatment provided to Medicare patients, especially those whose cost of care is likely to exceed available payment. Early studies of the effects of PPS reveal that the average length of stay in hospitals has continued its pre-PPS decline. While the potential cost savings to Medicare are significant, serious questions have been raised about possible negative effects on access to and the quality of care.

Quantity v. Quality of Life

Advances in medical technologies provide considerable ability to alter the timing and circumstances of death. Indeed, modern diagnostic and therapeutic technologies have changed the very definition of death and have influenced both professional and popular expectations. Recognition of the manipulability of death enables us to presume a significant measure of control and to contemplate a death that is more or less "acceptable."

Questions about life-sustaining medical care frequently revolve around judgments about what constitutes acceptable "quality of life" (and, implicitly at least, "quality of death") and deep-seated beliefs about the relevance of this consideration. Evaluations of "quality" are subjective and personal: what is an acceptable quality of life to one person may be a fate "worse than death" to another. Similarly, life-sustaining treatment that some would gladly endure, others would reject as "too burdensome" or "undignified." Thus, it is clear that references to the quality of life must distinguish whether the referrent is the patient's unique experience and evaluation of their own life or the vicarious experience and assumptions of some other person.

Many people believe that life, whatever its quality, is sacrosanct. Under this view, the possibility of sustaining life justifies, or even dictates, the use of all potentially effective means. In contrast, many other people believe that the present and expected future quality of life are valid, even essential, considerations in decisions about whether or not to apply life-sustaining treatments. These fundamental disagreements about quality v. quantity are frequently expressed in the terms of treatments that "prolong life" v. treatments that "prolong dying." In fact, the distinction between prolonged life and prolonged dying is like the difference between the proverbial glass that may be seen either as half full or half empty. The actual referrents are the same. (In this assessment, OTA uses the terms "prolonged life" and "prolonged dying" only when quoting other sources.)

Accompanying new attitudes toward death, and contributing to them, is the dramatic shift in the place of death. While the majority of deaths used to occur at home, by 1984, 61 percent of all deaths in this country occurred in hospitals and other medical centers. This shift has major implications for the types of care available to patients, the identity and number of persons involved in their care, and the kinds of decisions that must be made. Ironically, while hospitals were once feared as "places to die" because so little could be done to avert death, some people now fear hospitals as places to die because so *much* can be done.

SELECTED FINDINGS

Summarized below are the findings OTA deems most significant either because they relate uniquely to elderly persons, affect large numbers of citizens, have legislative implications, or make original contributions to the debate about life-sustaining technologies. The findings are presented under four general categories: 1) current and future resource use; 2) quality of care; 3) access to care; and 4) decisionmaking problems and processes. Further information on all these topics, as well as many more specific findings, appear in chapters 2 through 10 and in background papers associated with this assessment.

For the most part, the findings presented here apply to all of the technologies OTA studied—but they would not have been evident, or not documentable—without focusing on individual technologies. Thus, an overriding conclusion of this project is that **assessments of individual technologies can provide information for both public policy and clinical decisionmaking that abstract considerations of life-sustaining technology cannot.** Future studies and debate about health care decisionmaking might usefully adopt this more focused approach.

Current and Future Resource Use

Finding: Data on current utilization of life-sustaining technologies are highly unreliable. Future utilization cannot be accurately predicted.

OTA's attempt to estimate the utilization of five life-sustaining technologies reveals, above all, shortcomings in the available data and existing data collection systems. With the exception of the data collected and maintained by the Health Care Financing Administration (HCFA) on Medicare's End Stage Renal Disease program, reliable data on the numbers of patients are not available.

Estimates of the total number of patients of all ages and the number of elderly patients treated with dialysis, resuscitation, long-term mechanical ventilation, and nutritional support are shown in table 1-1. Total utilization ranges from a few thousand persons, in the case of mechanical ventilation, to 1.4 million persons, in the case of nutritional support. Utilization among elderly persons ranges from approximately 2,200 for ventilation to 680,000 for nutritional support. With the exception of the dialysis data, these figures should be regarded as preliminary, probably minimal, indicators of the size of the respective patient groups. The dialysis data are taken from HCFA records; the other data are based on a combination of industry estimates, published reports, and OTA contractor reports, and were compiled by OTA.

For life-sustaining antibiotic therapy, numerical estimates of utilization are too tentative to report. Although some data exist on the use of antibiotics in general, the number of cases in which treatment is life-sustaining, and the number of patients who are elderly, cannot be estimated.

Differences in data collection methods, definitions, time periods, etc., dictate special caution in comparisons of data for the individual life-sustaining technologies described in this report. (The reader should not conclude from table 1-1, for example, that 1 in 100 resuscitated patients requires prolonged mechanical ventilation or that 20 times as many people are treated with dialysis as mechanical ventilation.) The figures reported for mechanical ventilation are cross-sectional data; they do not reflect the fact that new morbidity creates a constant stream of patients, i.e., the patients on mechanical ventilation at the time these data were collected might be replaced several times over during the course of a year. The data for dialysis, on the other hand, represent all patients treated during a calendar year.

Also, patients with life-threatening medical conditions may be treated, simultaneously or sequentially, with several life-sustaining technologies. Many ventilator patients require nutritional support, and it has been estimated that 45 percent of all infections acquired in hospitals (*nosocomial* infections) are related to medical devices. Thus, totaling the number of patients receiving each of these life-sustaining technologies would overstate

Table 1-1.—Utilization of Life-Sustaining Technologies for Patients of All Ages, and for Elderly Patients, in All Settings Combined

	Total number of patients (all ages)	Patients over 65	
		Number	Percent of total
Dialysis[a]	90,621	27,641	31%
Resuscitation[b]	370,000 to 750,000	204,000 to 413,000	55% est.
Mechanical ventilation	3,775[c] to 6,575[d]	1,250[c] to 2,200[d,e]	34%
Nutritional support[f]	1,404,500	680,000	48% est.
Enteral (tube)	848,100	450,000	53% est.
Parenteral (intravenous)	556,400	230,000	40% est.

[a] 1985 HCFA data for Medicare's ESRD program.
[b] Contractor estimates, hospitalized patients only.
[c] 1985 data for 37 States, patients dependent on ventilator 14 days or longer.
[d] National estimates extrapolated from survey in Massachusetts.
[e] Elderly defined as over 70.
[f] 1984 industry data and contractor estimates.

SOURCE: Office of Technology Assessment, 1987.

the number of patients receiving *any* life-sustaining technology. In addition, the data in table 1-1 leave out patients who were treated, but too briefly to appear in the figures (e.g., patients ventilated for less than 14 days).

Future demand for life-sustaining technologies cannot be predicted without accurate information on current utilization and monitoring of changes in use. This problem is vividly illustrated by the brief history of Medicare's ESRD program. Prior to Medicare coverage for dialysis, the number and distribution of dialysis machines and personnel were so limited that treatment was available only to the wealthy and the hand-picked; patients over age 45 were seldom considered. Following enactment of Medicare's ESRD program, the number of dialysis patients of all ages climbed from 5,000 to over 90,000 between 1972 and 1985 (and the number of patients over 65 multiplied by at least a factor of 25)—figures far in excess of the original projections.

Future utilization of life-sustaining medical technologies will be influenced by a number of factors, some of which work in opposite directions. The aging of the population, improvements in the technologies, and availability in new settings will drive increased demand. Although these increases may be great, they are likely to be tempered by cost-containment measures, preventive strategies for specific diseases, changes in procedures and guidelines for treatment decisions, and changes in public attitudes. Increasingly, cries for "death with dignity" and the "right to die" are associated with the rejection of high-technology interventions near the time of death.

Finding: For resuscitation, mechanical ventilation, dialysis, nutritional support, and life-sustaining antibiotic therapy, persons age 65 and older constitute large proportions of all patients, but small proportions of the total elderly population.

This finding can be stated with confidence despite the numerous caveats about specific numbers. While persons 65 and older constitute about 11 percent of the total U.S. population, they comprise over 30 percent of all patients receiving dialysis, nutritional support, and mechanical ventilation (see table 1-1). In hospitals, an average of 55 percent of all patients who are resuscitated are elderly. In addition, because elderly persons are known to be at the highest risk for life-threatening infections, it is reasonable to assume that they also comprise a large proportion of individuals receiving life-sustaining antibiotic therapy.

It is important, however, to keep these findings in perspective. While the vast majority of nursing home patients receiving nutritional support are elderly, only 5 percent of all elderly persons are in a nursing home (at any one time), and only a small proportion of nursing home residents (2 to 5 percent) receive nutritional support. The proportion of elderly persons who receive other life-sustaining technologies is much smaller.

Finding: The costs associated with life-sustaining interventions are uncertain, but certainly high.

In general, available data on the costs of life-sustaining technologies are piecemeal and not comparable. The best data are those compiled by HCFA on the ESRD program. For the other technologies OTA studied, even the concept "cost" has been interpreted inconsistently, depending on *whose* costs are of concern. Thus, some publications that claim to report "costs" actually describe what economists call "charges" (i.e., billed amount) or "expenditures" (i.e., payments). Some reports include in their accounting only the specific services and supplies essential to the life-sustaining technology; others count the total cost of the hospital stay during which a life-sustaining technology is used. There has been no attempt to quantify the full economic impact using a definition of costs that includes factors like lost income of the patient or of family caregivers. What is clear is that the costs to providers, charges to patients, and expenditures by patients and third-parties for life-sustaining technologies *all* are high.

The total cost of care is closely associated with how long the life-sustaining technology is needed. Less obviously, **the costs associated with the initial life-sustaining intervention may be dwarfed by the ongoing costs associated with survival of patients whose health care needs remain great despite or because of the inter-**

vention. This is the case, for example, for severely debilitated people who acquire a life-threatening infection that is effectively treated with antibiotics and who subsequently require an extended stay in a nursing home. Their health and quality of life may remain poor, despite continuing institutionalization and health care.

Another major correlate of cost is the setting in which care is provided. (It must be recognized, of course, that the services, equipment, and expertise available in hospitals v. nursing homes v. the patient's home are not the same.) It is generally assumed that cost (along with charges and expenditures) is highest in the acute care hospital and lowest at home. The movement of high-technology care outside of ICUs and outside of hospitals altogether has been encouraged by, among other things, efforts to reduce health care expenditures. For patients whose needs can be met by a combination of self-care and unpaid family members, with only occasional professional attention, the charges and expenditures for home care are certainly below those associated with hospital care. However, if round-the-clock professional nursing and other attributes of intensive care are needed, it can actually cost patients and payers less to keep the patient in the hospital ICU than to try to "bring the intensive care unit into the home." Similarly, care in a nursing home sometimes costs less than care at home.

Available data on *charges* associated with the use of three life-sustaining technologies in the hospital and in community settings (including home care and other community settings), as reported in published studies and OTA contractor reports, are summarized in table 1-2. These data show the wide range in charges for one technology versus another, for hospital versus community care, and for different patients within each setting. Daily charges for life-sustaining treatments range from $4 to $500 for different forms of nutritional support. The most expensive of these technologies is mechanical ventilation, with average daily hospital charges of more than $800.

For life-sustaining antibiotic therapy and resuscitation, available data are particularly sketchy. Intravenous antibiotics are estimated to cost $30 to $200 per day, exclusive of the cost of any professional services or institutionalization. For resuscitation, OTA found no reliable cost estimates at all.

Table 1-2.—Charges for Life-Sustaining Technologies

	Hospital inpatient	Community setting
Dialysis		
Per treatment	—	$68-$200
Per year	—	$20,000-$30,00
Nutritional support		
Enteral		
Per day	$4-$132[a,b]	—
Per year	$1,450-$28,200	$3,000-$12,000
Parenteral		
Per day	$25-$500[b]	—
Per year	$9,125-$182,500	$50,000-$100,000
Mechanical ventilation		
Per day	$824[c]	—
Per year	$300,760[c]	$21,235-$216,000

[a] Daily hospital charges for enteral nutrition average $43; for parenteral nutrition the average charge is $196 per day.
[b] Includes formula, equipment and staff time, not hospital stay; 1985 data.
[c] Average charges, including hospital stay, for patients in 37 States; 1985 data.

SOURCE: Office of Technology Assessment, 1987.

Until accurate data are available on the costs and utilization of life-sustaining technologies and until the factors that alter cost and utilization are better understood, health care planning and public policy will be uninformed. Accurate baseline data and projections of demand for life-sustaining treatments are basic to planning of health care facilities, professional training, community resources, technological research and development, and decisions about coverage and reimbursement, including catastrophic health insurance plans. **Better information is also a prerequisite to serious discussion about the need for, or criteria to be used in, rationing of access to health care.**

Finding: Reimbursement is a major determinant of specific treatment options.

Most of the five technologies OTA studied encompass several treatment options, more than one of which might be suitable for a given patient. For some patients with chronic renal failure, either transplantation or dialysis might be appropriate, and then, more than one method of dialysis might be effective. For some patients who require ventilatory support, either positive pressure or relatively simple, negative pressure devices might be appropriate; similarly, for some patients, nutritional support and antibiotic therapy may be provided effectively by any one of several routes. The availability and level of reimbursement for certain technologies not only influence incentives for treatment v. nontreatment; they also influence the relative utilization of different treatment options. For example, some nutritional support experts believe that higher reimbursement for TPN results in its use for some hospitalized patients for whom tube feeding would be an effective, less expensive option.

The availability and level of reimbursement also determine which settings are available, sometimes encouraging inefficient use of resources or precluding use of the least restrictive environment. Between 1972 and 1982, the reimbursement structure of Medicare's ESRD program encouraged center- and hospital-based dialysis over home care. Medicare coverage for nutritional support of less than 90 days and Medicare coverage for drugs, including intravenous antibiotics, is not available to patients at home. The lack of reimbursement for short-term nutritional support and intravenous antibiotics creates purely financial reasons for continued hospitalization. Similarly, reimbursement for TPN and for mechanical ventilation is sometimes so much more complete for patients who remain in the hospital that **some patients who are well enough to go home cannot afford to do so**. The number of hospitalized elderly (and younger) patients needing life-sustaining technologies who could be safely treated in community settings is unknown.

Finding: The expansion of life-sustaining technologies to settings other than the acute care hospital has major implications for who and how many will receive treatment.

Currently, the numbers of elderly patients receiving life-sustaining treatments in their own homes, in nursing homes (tube feeding and antibiotics are exceptions), and in other nonhospital settings are relatively small; the overall numbers have been increasing, however, and many observers predict that this trend will continue. If life-sustaining technologies become widely available in nursing homes and patients' homes, they may be offered more readily, to more patients and different kinds of patients, and they may also be more readily accepted by patients who now would refuse them. Some observers warn that increased availability of life-sustaining technologies in nonhospital settings, especially if it is accompanied by increased reimbursement, could lead to serious overuse.

In general, patients who can be cared for in their own home enjoy benefits that contribute to their quality of life. In contrast to patients in the more restrictive and strange environments of hospitals and their ICUs, some chronic ventilator patients, home dialysis patients, and home nutritional support patients retain a certain amount of independence, despite physical dependence on technology. Even for patients whose functional ability is severely limited, care in their own home allows them to maintain considerable control over their health care and other aspects of their life, including social relationships.

The number of elderly persons who can be maintained on life-sustaining technologies in their own homes is limited. Complex home care requires, at a minimum, a patient who is medically stable and cooperative, capable and dedicated family members or companions, a suitable physical environment, support services in the community, and adequate reimbursement or personal financial resources. These conditions, difficult for patients of any age to meet, probably preclude most elderly patients. For mechanical ventilation, about 34 percent of patients of all ages, but only 14 percent of elderly patients are cared for in their own homes. It must be recognized, however, that the feasibility of home care for elderly patients varies with the technology that is needed. For TPN, 20 percent of home care patients are elderly. And, for tube feeding, it is estimated that as many as 55 percent of all home care patients are elderly.

There are numerous impediments to the optimal distribution of patients across settings. Some patients who could be safely transferred to nonhospital settings remain in hospitals, often indefinitely, because caregivers are not available for home care or because of a lack of services and facilities within their community. There is a scarcity of nursing home beds for technology-dependent patients because few nursing homes have adequate staff (or adequate incentives to develop staff) to provide the level of care these patients require. Some physicians and institutions remain unaware or unconvinced about the home care option and do not present it to patients. Some patients who have been discharged home have been forced to return to the hospital because of superior reimbursement in that setting. Information and service networks need to be developed to help ensure that all settings that are medically safe receive consideration.

Finding: For many patients, life-sustaining treatment in the acute care setting creates the need for chronic care and continuing technological support.

Because life-sustaining technologies seldom cure the underlying condition or restore normal physiological functioning, some patients who survive an acute intervention require continuing treatment for the rest of their lives. Acute dialysis or acute ventilation may evolve into prolonged, chronic, or permanent need for these technologies, with or without potential for rehabilitation. Chronic dependence on a life-sustaining technology is accompanied by continuous need for services or facilities that are typically both expensive and scarce.

Individuals who must remain institutionalized occupy a bed in the ICU, hospital, or nursing home, utilizing facilities, personnel, equipment, and other resources for which other patients may be competing. Individuals who are able to return to the community have needs that include reliable sources for medical equipment and supplies, professional and nonprofessional caregivers (including family members and other assistants), and maintenance and repair of equipment. One aspect of this continuing need is the high, and ongoing, cost of care. Another crucial aspect is that the necessary services and the linkages to coordinate them are unavailable in many communities.

A patient's need for long-term technological support is often difficult to predict, but this possibility must be recognized when the initial decision to provide acute care is made. Some argue that it is unethical to provide health care to acutely ill patients if society lacks the commitment also to provide chronic health care and related services—especially if those needs were created by the acute intervention. The discontinuity in existing health care services leaves some technology-dependent patients and their families in a predicament that they did not foresee when faced with the initial treatment decision.

Coordinated systems of care for technology-dependent persons exist in some European countries, and these models may be instructive. In France and in England, for example, systems are in place to provide comprehensive services that enable chronic ventilator patients to remain in their communities. These are regional programs that provide services ranging from group purchasing of medical supplies to equipment repair, patient education, and emergency care. In existence for more than 20 years, these systems are said to be economical and to improve the quality of life for these patients.

Quality of Care

Finding: There are some questions about the quality of care related to the use of life-sustaining technologies, particularly for elderly patients.

Although OTA did not specifically seek information related to the quality of care, some issues emerged. Perhaps most important, **there is ample evidence that some treatment options or procedures should be tailored to age, but there is little evidence that they are.** Despite the fact that age-related changes in the metabolism of drugs are now well recognized, for most antibiotics, dose and dose interval remain standard regardless of the patient's age. Similarly, although it is well established that nutritional requirements change with age, the details are not well understood, and nutritional formulas are frequently not adjusted to these changes, especially for patients on tube feeding. For the other life-sustaining technologies OTA studied, the possibility that the clinical outcomes for elderly patients might be improved if modifications were made either in the equipment or procedures has barely been addressed. Modifications in these treatments to account for age-related differences depend on continuing basic research in gerontology and other fields and on dissemination of this knowledge through professional training.

The traditional bias of medical education and practice places the cure of acute illness above all other goals. When cure is not a realistic goal, this approach often leads to inappropriate treatment decisions. Recent changes in the curricula of many health professions recognize this problem and seek to improve care by acknowledging and focusing on achievable goals, such as maximization of the patient's functional capacity and the quality of life. Pertinent curricular innovations include new courses in geriatrics, medical ethics, humanities, and death and dying.

Other quality of care issues result from shifts in the settings in which life-sustaining technologies are applied and changes in the personnel who are responsible for care. In nonhospital settings, responsibility for patient care is often entrusted to less trained professionals and to laypersons. The education and supervision of patients providing self-care, family members, and other lay caregivers, as well as home health care professionals are important issues. Health care personnel trained in the use of complex technologies have typically not been trained to work in community settings or to work with elderly persons. Maintenance and repair of equipment and availability of backup equipment can also be problems when life-sustaining technologies are used outside the hospital.

A different kind of quality of care issue concerns the technological hardware for certain life-sustaining technologies; this includes the primary medical device as well as the various peripheral supplies and components (e.g., tubing, solutions, power sources). Questions have been raised about the quality, safety, and suitability of some enteral formulas for nutritional support. Also, the Food and Drug Administration (FDA) has received a large number of reports of mechanical ventilators that have malfunctioned or failed. In some cases, only voluntary standards apply to the manufacture of devices and products used to sustain life.

Finding: Technological developments have improved the safety and efficacy of life-sustaining technologies, as well as the quality of life for some patients who are dependent on them.

Research and development (R&D) in many arenas, including physiology, medicine, engineering, electronics, biofeedback, and computer science, have brought continuous change in existing life-sustaining technologies as well as completely new technologies to sustain life (see app. C). Stimulated by competition for health care markets, perceived need to improve available products, regulatory standards, etc., R&D within the public and private sectors has resulted in more and better devices and methods for diagnosing, monitoring, and treating severely ill patients in both traditional and nontraditional settings.

General technological advances (e.g., miniaturization, computerization, new materials, and automation) have made possible improved efficacy, safety, and reliability of many medical devices. One example is the development of automatic blood gas analyzers, considered a watershed in mechanical ventilation technology. Other kinds of technological developments have meant improved comfort and independence for some patients. Innovations that reduce the size and weight of equipment, extend time between treatments, reduce the need for professional services, or make home care possible enhance the quality of life for many patients. Improved blood access systems for hemodialysis are a good example. Prior to development of the Teflon shunt in 1960, patients had to undergo the inconvenience, discomfort, and risk of infection associated with having a new surgical procedure for every dialysis treatment.

A potential benefit of continuing R&D is cost reduction. New methods of manufacture, new materials, and new markets may lower the production cost of certain equipment and supplies. If lowered production costs are reflected in prices or in reimbursement, this would result in lower treatment costs for some patients. Existing incentives to develop medical technologies that are less expensive and incentives to substitute lower for higher cost technologies appear largely tied to interest in the home health care market.

Access to Care

Finding: When resources are available, patients with life-threatening conditions are more likely than not to receive aggressive treatment.

The acute care orientation in medical training and practice emphasizes cure and prolongation of life and justifies "doing everything humanly possible" to achieve these goals. This *bias to treat* appears to prevail for patients of all ages. It has been reinforced by the wide availability of life-sustaining technologies in hospitals, reluctance to consider cost as an appropriate factor in individual decisionmaking, health professionals' and institutions' fear of legal action, and the weighty uncertainties surrounding treatment decisions. Since a wrong decision is irreversible, most health professionals would choose to "err on the side of life."

While withholding of treatment is resisted, withdrawal may be even more so. Despite wide agreement among ethicists and legal scholars that there is no theoretical basis for distinguishing between withholding and withdrawal of life-sustaining technologies, **in actual practice it is frequently *easier* to withhold a life-sustaining treatment whose benefit is uncertain than later to "pull the plug," even when the patient or patient's surrogate requests this.** Grief, guilt, and health professionals' feelings of failure at times prevent rational decisionmaking.

Some health professionals and family members view withdrawal of aggressive medical treatment as "giving up" or even "abandonment" of the patient. On the other hand, some believe there is a greater moral imperative to withdraw treatment that proves to be futile or unwanted than to initiate an intervention that is of uncertain value. This position emphasizes the need for continual reevaluation of the medical indications for treatment. Some persons who hold this view advocate the use of *time-limited trials*. For example, mechanical ventilation could be instituted with the provision that its use be reconsidered after 1 week; dialysis could be tried for 4 months, etc. After a designated trial period, the patient's situation could be thoroughly evaluated; there would be an opportunity to assess the value of treatment and to ascertain the patient's wishes.

In addition to philosophical and psychological difficulties, practical difficulties at times discourage the withdrawal of life-sustaining technologies. To withdraw most life-sustaining treatments requires a specific physician order, frank and time-consuming conversations with the patient and/or family, conferences among members of the health care team, and formal documentation in the patient's record. At times, institutional review committees, ethics committees, legal advisers, or the courts become involved in decisions to withdraw treatment. While decisionmaking procedures vary with the technology being considered, the decision to withhold treatment is generally less explicit than the decision to withdraw it.

Finding: Relative access to life-sustaining technologies by different segments of the population cannot be assessed with available data.

Health professionals' preference to provide rather than to withhold treatment and to withhold rather than withdraw it are competing biases whose impact on access to life-sustaining treatments is not clear. Many other factors, notably reimbursement, also influence accessibility of health care and determine whether or not various segments of the population have equal access. Between 1965 and 1983, Medicare's cost-based reimbursement system facilitated the development and diffusion of medical technologies in general, and made life-sustaining technologies available to hospitalized elderly patients with little regard to cost. It is not yet clear what impact Medicare's prospective payment system for hospital care has had on accessibility of life-sustaining treatments. Available utilization data prove that elderly persons have *considerable* access to life-sustaining treatments, but utilization data alone do not permit conclusions about whether access is restricted (leading to undertreatment) or excessive (leading to overtreatment).

Public opinion and concerns expressed by health professionals suggest that overtreatment—i.e., provision of treatment that is or becomes unwanted or unbeneficial—is more frequent than undertreatment. In 1985 the National Institutes of Health cosponsored a conference on Withholding and Withdrawing Mechanical Ventilation in response to wide agreement among clinicians that the technology is too often started and too often continued inappropriately. It should be noted, however, that because treatment is easier to count than nontreatment, overuse is probably more visible than underuse.

Cost-containment pressures in general and Medicare's prospective hospital payment system in particular force health care decisionmakers to acknowledge that resources are limited and that all patients cannot have "everything possible." The pressure to reduce costs has spawned legitimate concerns among health professionals and the public that every patient will not have everything that is *desirable*. In the absence of guidelines for how costs are to be reduced, it is unclear which patients will be affected the most. Since Medicare is a program for elderly citizens, however, the patients most directly affected by hospitals' and physicians' efforts to reduce health care costs under Medicare are those over 65.

It appears that questions about equality of access should not just make the usual comparisons of rich and poor, old and young, or black and white. Pertinent concerns also include setting, cognitive ability, and age subgroup. Anecdotal evidence and small studies suggest that a nursing home resident with a life-threatening infection is less likely to be treated than if that same person were in an acute care hospital; persons with severely impaired cognitive ability—whose quality of life is perceived to be poor and who cannot speak for themselves—are also less likely to receive aggressive treatment; relatively young elderly persons and those who have a spouse are more likely to be treated than those who are older or alone.

Since 1983, evidence of changes in hospital admission policies and the continued reduction in length of stay suggest that limited Medicare payment may have begun to influence treatment options that are made available. Some Medicare patients whose treatment costs are expected to exceed payment for their diagnosis-related group (DRG) have been dubbed "DRG losers," and there is mounting anecdotal evidence that some persons have been denied admission to certain hospitals or denied admission to the ICU.[3] **Despite financial incentives to limit expensive care, however, there is no evidence to date that PPS has reduced access to *life-sustaining* treatment.**

As cost-containment measures are implemented in Medicaid and in private health insurance programs, patients of all ages are more likely to receive reduced care. It remains to be seen whether savings are or will be found by cutting services to all patients or by cutting services to particular groups of patients. There is wide agreement that, under PPS, Medicare patients are being discharged from hospitals "quicker and sicker." At the same time, however, Medicare patients who are retained in hospitals are also sicker *and older* than before PPS. The meaning of these findings and the extent to which they are caused by PPS is a subject of considerable debate that is outside the scope of this assessment.

Finding: For patients who do not want life-sustaining technologies and patients for whom these technologies are not medically indicated, treatment options have been relatively unexplored and are not widely available.

Treatments whose goal is to control pain and suffering, even at the risk of hastening death, are regarded by many people as reasonable alternatives to aggressive life-sustaining medical treatment. There is anecdotal evidence, however, that patients who refuse life-sustaining treatment that is offered and patients from whom aggressive treatment has been withheld or withdrawn are sometimes neglected by health professionals. Persons capable of providing alternate forms of treatment—especially hospice care and palliative or supportive care—may not be available. Also there are legal and ethical uncertainties regarding when and how it may be appropriate to limit treatment. Medicare reimbursement for hospice care is currently available only in special circumstances, only to patients who have been diagnosed as "terminally ill" and then, of course, only where hospice facilities and/or personnel are available.

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[3] A study in one hospital found that Medicare patients in specified circulatory system DRGs, who were treated in the ICU, resulted in losses to the hospital ranging from $674 to over $24,000 per discharge. Such dramatic effects have attracted considerable attention among health professionals and institutions.

Decisionmaking Problems and Processes

Finding: Decisions about the use of life-sustaining technologies are made amid great uncertainty regarding the likely clinical outcomes.

Decisions about whether or not to institute life-sustaining treatments would be relatively easy if it were known in advance whether or not the patient would survive, for how long, and in what condition. But, variations in patients' physiological and psychological adjustment, and in the quality of care they receive, make highly uncertain the outcomes of any treatment for any given patient. Pervasive *prognostic uncertainty* means it is impossible to predict whether or not any treatment will be effective, whether a particular treatment is optimal, or whether a patient would survive without treatment.

The inability to prospectively identify patients who will benefit from treatment arises because, contrary to popular belief, **life-sustaining technologies are frequently ineffective. For acutely ill patients of all ages, aggressive treatment is associated with high mortality and serious complications.** At best, one-third to one-half of all in-hospital resuscitation attempts succeed; and only one-half of the patients who are successfully resuscitated survive long enough to be discharged from the hospital. In acute episodes of respiratory failure, adults treated with mechanical ventilation have about a 50-percent chance of surviving; for acute renal failure, only 20 percent of persons over age 70 survive. Patients receiving antibiotic therapy or nutritional support have a relatively high, but not necessarily predictable, chance of survival.

Prognosis is often especially difficult when the patient is elderly. The interaction of disease (especially multiple coexisting diseases) with reduced physiological reserve makes diagnosis in elderly patients difficult and responses to treatment particularly difficult to predict. The clinical uncertainties may be exacerbated by the shortage of basic scientific knowledge about aging and the shortage of personnel trained in geriatric assessment and care.

Inability to accurately predict the outcomes of particular treatments can result in two kinds of errors—i.e., treatment of patients for whom treatment is futile and failure to treat patients who would survive. Reducing both kinds of errors would not only avoid useless suffering for patients and families, but is tantamount to more rational and efficient use of health care resources. Studies of the outcomes of critical care have shown that the cases in which costs are highest are those in which the outcome was inaccurately predicted.

Basic and clinical research are among the necessary approaches to reducing clinical uncertainty and, thereby, to improving the content of treatment decisions. Information is needed about the physiological and psychological responses of elderly patients to particular treatments as well as information about the outcomes *without* treatment. Dissemination of this information through education and training of health care professionals would strengthen their ability to evaluate, and to help patients understand, the relative risks and benefits of treatment options.

Research is underway on a variety of methods to combine diagnostic and treatment data into statistical categories that are associated with known probabilities of survival. Theoretically, reliable classification systems could provide physicians an improved basis for predicting the outcome of treatment. An OTA workshop on such systems of patient classification, held in conjunction with this assessment, concluded that, although the current state-of-the-art is limited and systems remain experimental, there is reason to believe that refined patient classification systems will effectively reduce clinical uncertainty and provide valuable help in making some kinds of treatment decisions.

Finding: For an individual patient, chronological age is a poor predictor of the outcome of treatment with life-sustaining technologies.

The statistical odds of survival are worse for elderly than for younger adults who receive a life-sustaining intervention, but neither age 65—nor any single age criterion—is an adequate predictor of physiological or psychological response to treatment. Moreover, because physiological and psychological diversity increase as people age, response to particular technological interventions may be *hardest* to predict in the oldest patients.

Available data for most of the life-sustaining technologies OTA studied substantiate that elderly patients, as a group, have lower survival rates and more complications. With dialysis, for example, the mortality rate among elderly patients is three times as high as that for all patients (45 v. 15 percent). On the other hand, elderly patients, on the whole, seem to make a better psychological adjustment to chronic dialysis than do younger patients. Generalizations based on the patient's age, while they may be statistically accurate, obscure the fact that many individual elderly patients survive and thrive after treatment with a life-sustaining technology.

For patients of all ages, life-sustaining technologies are associated with numerous potentially serious complications. It has sometimes been assumed that elderly persons, as a group, are at higher risk of such complications and that the complications elderly patients experience are apt to be more serious. In fact, data to support this assumption are inconclusive and vary with the technology. For example, while increased risk of rib fractures is frequently mentioned in connection with resuscitation of elderly persons, OTA is unaware of data to support this. Moreover, any statistical association between age and rib fractures is due not to age per se, but to age-related diseases that make the bones brittle (e.g., osteoporosis).

To some degree, the worse outcomes of elderly patients may stem from inadequate expertise regarding aging and geriatric care. Health professionals' inattention to or misinterpretation of pertinent clinical information can lead to unwarranted generalizations about elderly patients and to a self-fulfilling prophecy. If it is reasoned, for instance, that an elderly person should not receive aggressive life-sustaining treatment "because he won't do well," he is almost certain to not do well!

Most of the patient classification systems OTA reviewed include chronological age as one variable in the statistical prediction model. Even in these abstract mathematical models, **age contributes less to the prediction than other patient characteristics, including severity of illness, diagnosis, or previous health status.** So great is individual variability that some researchers and clinicians argue that the patient's age should be disregarded in making treatment decisions. Others advocate development of a proxy for age that more accurately reflects the health status and reserve capacity of individual patients.

Finding: The legal and ethical uncertainties that surround decisions about the use of life-sustaining technologies have led to intense interest in the development of decisionmaking supports and guidelines.

Profound ethical uncertainties in decisions about life-sustaining technologies emanate from the plurality of cultural and religious orientations that characterize this society and that affect people's values and beliefs about such fundamental things as the meaning of life and the meaning of death, individual v. public good, and the quantity v. quality of life. Ethical quandaries may make it difficult to discern the goal of the decision (e.g., patient autonomy v. survival, etc.), the means to achieve it, or both.

Grave legal uncertainties arise because there are situations in which no pertinent legislation exists, because legislation differs in different jurisdictions, and because the law is changing. Legal precedent and case law offer valuable, but not always consistent, guidance. Uncertainty about what actions are legal fuel health professionals' widespread fear of the law, and fear of malpractice litigation is an important factor in clinical decisionmaking. Some of this fear is well founded; some, however, results from health professionals' ignorance or misinterpretation of the law.[5]

Decisionmaking problems are made still more complex by the fact that, in most cases, there is not one decision to be made (e.g., whether or not to start dialysis), but rather a series of decisions (e.g., whether to hospitalize, to do a particular diagnostic test, to put the patient in the ICU, to continue treatment, etc.). And, separate from the questions about what the decision should be are serious questions about how the decision should be reached. If, for example, the patient disagrees with medical advice, what should be done? If the patient is not decisionally capable, who shall be the surrogate? The variety in patients' physical status, decisionmaking capacity, severity of illness (emergency or not), social circumstances (especially whether one is in the community or in an institution), and family situation (especially whether or not there is a designated surrogate) mean that no single approach to decisionmaking can be applied in all instances. These difficulties have stimulated legislative, institutional, and professional responses.

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[5] See M.B. Kapp and B. Lo, "Legal Perceptions and Medical Decisionmaking," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, March 1986.

Possible roles of government in reducing the uncertainties surrounding decisions about life-sustaining technologies include Federal or State legislation and regulations and support for research. To date, the legal response has been primarily the enactment of new laws at the State level. Living will laws have been enacted in 38 States and the District of Columbia. All States and the District of Columbia have durable power of attorney statutes, and 15 States have statutes that specifically authorize the use of a durable power of attorney for health care decisionmaking. These advance directives protect the rights of patients to participate in health care decisions even after they become decisionally incapable and, by clarifying the patient's treatment preferences, offer health care providers a measure of protection as well. Family consent laws, that specify the right of family members to make treatment decisions for an incompetent person, are another option. In some States, courts have mandated specific procedures that must be followed in decisionmaking about life-sustaining technologies. Each form of legal response does a partial job of solving the problems that arise in decisions about life-sustaining treatment. The clinical and ethical dilemmas, of course, remain.

As recommended by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, some health care institutions, especially hospitals, have developed policies or guidelines that specify how decisions about life-sustaining technologies will be made. These attempt to ensure quality of care and to reduce risk to the institution and its staff. Always, institutional policies are subservient to existing State laws and mandates (or, in the case of some Federal institutions, Federal law) regarding advance directives, family consent, malpractice, etc. **In almost all cases, institutional policies are procedural, not substantive. That is, they emphasize how a decision should be reached, not what it should be.**

Acute care hospitals are the institutions most likely to have policies regarding decisions about life-sustaining technologies.[5] The hospital policies OTA has reviewed tend to be very cautious and to presume that treatment will be provided. Most focus on clinical criteria for particular treatments, especially resuscitation, and specify procedures for designating and implementing Do-Not-Resuscitate (DNR) orders. Some institutional policies specify alternate levels of care and then have a procedure for assigning patients to each level. Under this kind of policy, patients may be designated, for example, "do not resuscitate," "do not intubate," or "supportive care only."

Institutional policies make explicit the presumption for or against treatment in a facility, who will be involved in a treatment decision (patient, family, attending physician, other physicians, nurses, ethics committee, other facility staff), and how advance directives will be regarded. Institutional guidelines may address ways to protect patient autonomy, for patients who are decisionally capable and those who are not, and ways to resolve conflicts.

There is now some movement toward requiring policies as a standard for accreditation of institutions. In June 1987, the Joint Commission on the Accreditation of Hospitals (JCAH) adopted a standard requiring hospitals and nursing homes to have a policy for decisions about resuscitation by 1988.

Ethical analysis is increasingly recognized as a useful tool in making treatment decisions. Thus, another institutional response has been the establishment of institutional ethics committees or employment of a philosopher or theologian to assist in the resolution of troublesome cases. At least half of all acute care hospitals, and higher proportions of large hospitals and teaching hospitals, have established ethics committees to assist in decisionmaking for difficult cases. A few nursing homes have also established institutional ethics committees. Typically, these committees include physicians, nurses, administrators, attorneys, social workers, and lay persons who review specific cases brought to their attention. Individual institutional policies specify the role of these parties in the decisionmaking process. In most instances, decisions made by ethics committees are regarded as advisory.

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[5] A 1986 survey by the Joint Commission on the Accreditation of Hospitals found that 57 percent of acute care hospitals, 43 percent of hospices, and 20 percent of nursing homes have formal policies for decisions about resuscitaiton.

Associations of health care professionals have shown strong interest in developing decisionmaking guidelines themselves, partly in an effort to avoid government intervention. Some of these are clinical guidelines, specifying when a particular treatment is medically indicated. Some, notably the American Medical Association's (AMA) 1986 statement on "Withholding or Withdrawing Life Prolonging Medical Treatment," address the physicians' legal and ethical responsibilities in making these decisions. The AMA statement specifies that "life prolonging medical treatment," which "includes medication and artificially or technologically supplied respiration, nutrition or hydration" may be withheld or withdrawn when doing so is in the patient's best interest.

Another example of the interest in guidelines is the list of "principles for decisionmaking" developed by the advisory panel to this OTA assessment (see box 1-A). These express the strong convergence of opinion—but not unanimity—of a panel of physicians, nurses, lawyers, ethicists, and economists regarding many of the fundamental questions.

Finding: In practice, many patients are not involved in decisions about the use of life-sustaining technologies.

The patient's involvement in decisions about the use of life-sustaining technologies varies widely depending on the urgency of the medical event, the setting, the patient's cognitive status, and established decisionmaking procedures. For the technologies OTA studied, the patient's consent to treatment is frequently not obtained, and even when consent is obtained, it is frequently not "informed."

Sometimes the patient is left out of the decisionmaking process because the need for immediate action or the patient's mental state makes it impossible to do otherwise. Victims of cardiac or respiratory arrest, for example, are typically unconscious or in a severely compromised mental state; moreover, the imminent risk of brain damage does not permit time for discussion with other persons who may know the patient's wishes. In such emergencies, when the patient's consent for initiation of treatment is unobtainable, consent is usually "implied." Thus, emergency medical technicians responding to calls are usually obligated to try to resuscitate every victim of cardiac arrest, not to pause and ask whether this is wanted.

In the case of resuscitation, the bias to treat is so strong that the normal presumption about informed consent is reversed. That is, patients (or their surrogates) are likely to be consulted if a DNR order is being considered, but unlikely to be consulted for consent *to resuscitate*.

Cognitive impairment resulting from dementia or depression is another major factor in patients' involvement in treatment decisions. Patients who, based on formal or informal assessment, are considered to have severely impaired cognition are commonly excluded from decisions about their care. Some of these people, however, if given the opportunity, express consistent wishes regarding treatment v. nontreatment. Since the prevalence of dementia increases with advanced age, elderly patients as a group are less likely than younger adults to be able to actively participate in decisions about their care.

If a patient is determined decisionally incapable, a surrogate decisionmaker can be, and frequently is, designated. This may be done informally, as when the physician turns to the patient's spouse or an adult child. Or a surrogate may be formally appointed, by the patient or by a court. Some States specify a hierarchy of family members who have decisionmaking authority if a surrogate is needed; others have a "durable power of attorney for health care" statute.

Box 1-A.—Principles for Decisionmaking Regarding the Use of Life-Sustaining Technologies for Elderly Persons, as Developed by Project Advisory Panel

NOTE: *Members of the Advisory Panel to this OTA assessment (see title page) sought to express their strong convergence of opinion regarding many of the fundamental questions regarding the use of life-sustaining technologies for elderly persons. The following list of principles for decisionmaking was developed at the final meeting of the Panel, in February 1986. These are the personal views of the majority of Panel members, all of whom were present at the meeting or subsequently polled. It should be noted that dissent, while rare, was in some cases strong. These principles do not necessarily reflect the opinion of OTA, staff for this assessment, members of the Technology Assessment Board, or members of the assessment's requesting committees. With these caveats, the following principles are offered to Congress and the public for consideration.*

- An adult patient who is capable of making decisions has the right to decline any form of medical treatment or intervention. However, an individual does not necessarily have a right to unlimited medical treatment or intervention.
- Decisions regarding the use of life-sustaining treatments must be made on an individual basis and should never be based on chronological age alone. Chronological age per se is a poor criterion on which to base individual medical decisions; however, age may be a legitimate modifier regarding appropriate utilization of life-sustaining medical technologies.
- Diagnosis alone is a poor criterion for decisions about the use of life-sustaining technologies. Because of the great variability among patients with the same diagnosis, patient assessment must also include measures of functional impairment and severity of illness.
- Cognitive function is an important marker of the quality of life.
- The courts are not and should not be the usual route or determinant for making decisions about the use of life-sustaining technologies or for resolving the dilemmas these technologies may create.
- There is little need or room for Federal legislation concerning the initiation, withholding, or withdrawal of specific life-sustaining technologies.
- There is a major need for a clear, workable definition of the appropriate role of surrogates in health care decisionmaking, including the nature of their responsibilities and their suitability to make decisions.
- There is a need to recognize that a process exists, or should exist, for making decisions about the use of life-sustaining technologies. The process described by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research could serve as a model.
- A physician or other health professional who does not want to follow the wishes of a patient who is capable of making decisions regarding his or her treatment should withdraw from that case.
- Socioeconomic status should not be a barrier to access to health care, including life-sustaining interventions.
- There is an important need for education of the public and health care providers regarding the nature and appropriate use of life-sustaining technologies.
- There is a specific need for improved clinical information that would predict the probability of a critically or seriously ill patient's survival, functional status, and subsequent quality of life.
- There is a wide range of medical and legal disagreement and varying levels of emotional strain and moral conflict about the appropriate use of life-sustaining technologies. The great heterogeneity of the American population makes consensus difficult and increases the likelihood of formal institutional decisionmaking procedures.

In some cases, it is possible to obtain the patient's informed consent, but the treatment in question is considered so "ordinary" that standard practice diverges from the law requiring informed consent. Antibiotic therapy, especially in the hospital setting, is so routine that health professionals often consider consent unnecessary, and they do not seek it. Also, health professionals' perceptions of some interventions as ordinary or noninvasive mean that, **in practice, different treatment modalities for a single life-sustaining technology can involve different decisionmaking practices.** Thus, in many institutions, a nasogastric tube may be placed for the provision of enteral nutrition without the patient's consent—even though formal consent is always required for surgical placement of a gastrostomy tube for enteral nutrition or a catheter for TPN.

Many patients, particularly elderly patients, are accustomed to a passive role in the doctor-patient relationship and to accepting the advice of trusted health professionals without questioning. Persons who have developed this behavior over a lifetime cannot be expected to start seeking information or to take an active role in treatment decisions when those decisions are most difficult. A 1982 national survey reported that 38 percent of respondents of all ages, and 60 percent of elderly respondents, "want the responsibility of making the final choices about your medical treatment" to rest with their doctor. Some elderly persons prefer to entrust important treatment decisions to their spouse or an adult child.

The urgency of many life-threatening conditions and the fact that patients may be decisionally incapable at the time a treatment decision must be made point to the importance of determining patients' wishes about life-sustaining treatments *before a life-threatening emergency occurs*. Implementation of the patient's wishes is frequently dependent on advance planning. This may take several forms, including: discussions with family members and/or health professionals about treatment options, with documentation in the medical record or in a formal advance directive, such as a "living will"; designation of a surrogate decisionmaker; or institutional policies that ask patients to indicate their treatment choices upon admission.

Many health professionals believe that the goal of truly informed consent is often illusory even when there is time for discussion and the patient is fully in command of his or her cognitive faculties. In addition to the difficulty most laypersons would have in understanding the details of their condition and the treatment options, the gulf between hypothetical and actual situations is wide. It is unlikely, for example, that a layperson (or a health professional) who has not personally experienced mechanical ventilation can fully comprehend the impact of this treatment. By the same token, it is impossible to anticipate what it is like to be unable to breathe. Physicians' observe that many people "change their mind [about being intubated for mechanical ventilation] when they are choking to death," and this observation contributes to their skepticism about advance directives.

Even when the patient has been informed about treatment options and his or her wishes have been specified, problems remain in ensuring that these wishes are implemented, especially if they call for limited treatment. Neither an advance directive nor the instructions of a surrogate can be followed if authorities do not know one exists or if the document or person cannot be located. Advance directives that indicate refusal of life-sustaining treatment are sometimes overruled because they are considered "too vague." This can happen if, for example, the patient's circumstances or the treatment being considered was not anticipated when the directive was written, and physicians think treatment will be beneficial. Inconsistencies in State laws are a major problem. Some States will not recognize an advance directive that was made in another State. In many States, advance directives do not become operative until or unless the patient is diagnosed "terminally ill." Moreover, some State living will statutes include provisions that, in the view of some people, contradict the common law right to refuse treatment, by specifying, for instance, that nutritional support must always be provided. A patient preference that runs counter to the advice of health professionals is often interpreted as "irrational," and efforts will be made to change the patient's mind or to circumvent the patient's request. In such cases, the patient's decisionmaking capability may be called into question, and efforts made to appoint a surrogate or a guardian.

In general, consent to recommended treatment is easier to implement than is refusal of recommended treatment, and any patient wish is easier to carry out if it is consistent with the advice of caregivers and the wishes of family members.

Finally, **decisions about the use of certain noninvasive, common technologies are often made without consideration of their life-and-death implications.** Care of the life-threatened elderly involves a continuous series of treatment decisions which, individually, may seem so small and undramatic that their life-and-death implications are not even recognized. Decisions about the treatment of a life-threatening infection, even in severely debilitated and terminally ill people, frequently focus on choice of the appropriate antibiotic and omit explicit consideration of whether or not to treat.

Finding: The physical, psychological, and financial stresses associated with life-sustaining treatments are great, not only for patients, but also for family members and caregivers.

The physical, psychological, and financial stresses imposed by the life-sustaining technologies OTA has studied differ with the technology, and their significance depends on the personalities, specific resources, and exigencies of each case. Also, the immediate and short-term stresses are different from those associated with chronic care. Some patients cope admirably with the discomforts and fears associated with acute care and, if necessary, with a technology-dependent lifestyle, but others respond to the anticipated stress by refusing treatment. Others start treatment but eventually request that it be withdrawn; they may be depressed or even suicidal.

Specific effects of the technologies OTA studied include inability to speak or eat (mechanical ventilation), discomfort and limited mobility associated with tubes and catheters (whether for ventilation, nutritional support, drug delivery, or dialysis), and a gamut of complications ranging from minor to life-threatening. For patients who are acutely ill, loss of sleep, disorientation, and anxiety are concomitants of hospitalization and medication that may accompany all these treatments. Physical restraints, sometimes used for patients who are uncooperative or confused, are an additional source of distress. Fear of a new acute episode, loss of independence and control, dietary regimens, restricted activities, and financial worries may be among the long-term burdens for patients who are restored to medical stability. Comorbidities, reduced physiological reserve, and limited social support, i.e., characteristics of many elderly patients, may exacerbate any or all of these.

Family members and friends are also under great stress related to anticipatory grieving, financial burdens, and excessive demands on their time. Involvement in treatment decisions is likely to be filled with uncertainty, self-doubt, or perhaps guilt. If the duration of treatment is prolonged, and especially if the family has caregiving responsibilities, the lifestyle of family members may be radically changed. Emotional burdens may be especially great if the patient's condition or treatment impairs or precludes the ability to communicate or if treatment cannot be administered without physical restraints.

It is widely agreed that informed consent should include disclosure of the likely discomforts and restrictions attendant with use of these technologies. However, even if the patient is conscious and fully competent when the treatment decision must be made, the full impact of these treatments is difficult to predict and to convey. If the patient is unconscious or severely demented or confused, those entrusted with the treatment decision can only speculate about the patient's experience of pain or distress with (or without) any of these treatments.

Finally, caring for critically ill, terminally ill, or severely debilitated patients who may be treated with life-sustaining technologies is demanding and highly stressful for health care providers. In addition to the emotional load of dealing with very ill patients and grieving relatives, health professionals are constantly reminded of their own mortality and their fallibility. Emotional detachment from patients, avoidance of patients' families, and overuse of technologies are not uncommon responses. Impaired job performance and "burn-out" are also reported. Most health care professionals currently in practice received little or no training in the human aspects of death and dying; many are ill-equipped either to provide emotional support to dying patients or to cope with their own personal reactions.

Whether or not the experience of family members or caregivers should have any bearing on a treatment decision (or on who should be the surrogate) is an interesting ethical dilemma—which this assessment does not address. The point here is that patients may not be alone in their need for social and/or financial support.

Finding: Currently, the most controversial life-sustaining technology is nutritional support. The highly emotional reaction to this technology obscures specific clinical, legal, and ethical questions that require resolution.

Of all the life-sustaining technologies OTA studied, nutritional support and hydration is the most troublesome for ethicists, clinicians, and the public. It is over this technology that advocates of "death with dignity" and the "right to life," as well as more moderate positions differ most sharply. The debate centers around the question of whether tube and intravenous feeding and hydration are "food and water" or a medical treatment. In the former view, the provision of artificial nutrition and hydration constitutes a basic aspect of human caring that should be withheld or withdrawn only when death is imminent or when it is not medically possible to provide them. In the latter view, these are medical treatments that can be withheld or withdrawn under the same circumstances as other life-sustaining technologies. These opposing views leave little common ground for the formulation of policy or for decisions regarding the care of individual patients.

Very little is known about persons on long-term nutritional support, especially in nursing homes. Anecdotal evidence and some recent research findings suggest that many patients on long-term tube feeding are cognitively impaired, but it is not clear why they are tube fed—whether it is because they resist hand feeding, because of swallowing difficulties, or for other reasons. Some people claim that nursing home residents are tube fed because hand feeding is too time-consuming. There are, however, no data to substantiate this claim.

Lack of information about cognitively impaired people on long-term tube feeding is related to the general lack of information about cognitive impairment in elderly people. Ongoing biomedical and behavioral research on Alzheimer's disease promises to provide some answers. However, much more needs to be learned about the physiological, psychological, and emotional aspects of dementia—particularly the late stages of dementing diseases—in order to understand why some patients with these conditions stop eating and refuse hand feeding.

The patient's formal consent is usually not obtained for nasogastric tube feeding—by far the most common mode of nutritional support—because it is not "invasive." Although nasogastric tube feeding does not involve surgery, some people consider it burdensome, particularly when it is used for prolonged periods, sometimes years. An unknown proportion of people who receive tube feeding, including some who are cognitively impaired, are physically restrained to keep them from pulling out the tube. This combination of factors would seem to indicate a need for very rigorous decisionmaking procedures that include methods for ascertaining the patient's treatment preferences whenever possible, appointment of a surrogate decisionmaker when necessary, and periodic review of both the need for and the method of treatment.

Finding: Ongoing social and technological change will continuously alter the decisionmaking context.

The relatively brief history of life-sustaining technologies shows how rapidly and dramatically changes can occur in attitudes, expectations, and policies that determine their use. These changes are driven by a variety of social and technological factors that are in constant flux and that are often unanticipated.

At both the individual and societal level, decisions about the use of life-sustaining technologies for elderly people will be influenced by (and, in turn, will influence) changes in a wide variety of factors, including technological capabilities, scientific knowledge, medical education, economic conditions, public policies and laws, and public attitudes and expectations. Factors that have attracted considerable attention in recent years include the growth and aging of the elderly population, efforts to contain health care costs, and concern about the quality of life. Decisions about the use of life-sustaining technologies will also be influenced by the increasing level of education and sophistication among the elderly population, increased competition in health care, and an oversupply of physicians. Comprehensive national health insurance, a solution to the "malpractice crisis," and prevention of dementia are examples of more distant but equally significant future possibilities.

Improvements in existing technologies and new treatment modalities could improve the efficacy of treatments, reduce the chance of complications, and increase patients' comfort and independence. Technological developments might either raise or lower the cost of treatment. Other developments, including improved methods of pain control, and increased portability and self-care, as well as innovations like artificial eyes and ears, will improve the quality of life for chronically ill, disabled, and technology-dependent people. These marginal improvements and innovations could alter the balance of benefits and burdens of a particular technology and change attitudes about sustaining life in persons who are elderly and disabled. In some cases, treatment decisions might become easier and standards of practice might change, leading to increased use of life-sustaining technologies.

Some existing technologies will be wholly replaced. Just as kidney transplants eliminate the need for dialysis in individual patients, other organ transplants or artificial organs may eventually obviate the need for other life-sustaining technologies. Very widespread use of such "definitive" technologies could render today's "halfway technologies" obsolete. Further in the future, effective preventive strategies might have even more profound effects on human health and longevity. However, with respect to decisionmaking, the effect of this kind of technological development will be merely to push problems further into the future. If we learn to cure heart disease, we will still face cancer, stroke, and other potentially fatal diseases. We might eliminate one cause of death after another, but never all of them.

Neither the development of new technologies nor improvements in existing technologies are likely to make the fundamental issues of access, quality, and cost of care, or the decisionmaking dilemmas these create, go away. Instead, change will be in the foci and details of current ethical, legal, and clinical debates. OTA's analysis shows that the current intense interest in nutritional support follows more than a decade of controversy and court cases focused on mechanical ventilation. A possible next center of controversy is antibiotic therapy, which is only now gaining recognition as a life-sustaining treatment that raises serious issues. Similarly, changes in technology and in health services delivery will shift concern from the hospital to community settings and transfer more decisionmaking responsibility from physicians to other health care personnel and to lay caregivers.

In addition, **social and technological change will bring some new questions and intensify some of the current problems.** For example, as both the law and medical practice change, new kinds of legal challenges may arise. A recent instance in which physicians were charged because they instituted unwanted treatment is said to have opened the door to a new set of legal actions. The old problems of cost and access to care may be exacerbated if, as many people predict, the cost of providing the full range of theoretically beneficial treatments continues to increase. Particularly high cost will be associated with the care of individuals enabled to survive much longer than currently possible. Continuing high cost (and increasing cost) could lead to a more prominent role of third-party payers and government in health care decisionmaking.

Other pertinent developments will not change the basic decisionmaking problems but do promise to help us sort through difficult choices. These include the procedures, policies, and technological developments that aim to supply more complete information on which to base decisions and/or a more systematic way to assimilate it and reach an informed conclusion. These range from patient education to health professions education and from computerized decision support systems to ethical analysis.

CONGRESSIONAL ISSUES AND OPTIONS

The following issues and options are derived from information summarized in this chapter and presented in detail in the full report. They address problems that are common among several or all of the life-sustaining technologies OTA studied and that are realistic foci for congressional oversight and legislative activity. Problem areas that are unique to one or another technology and those that do not suggest Federal involvement are presented in the findings and implications at the end of each of the respective chapters. Ultimately, resolution of the diverse problems associated with the use of life-sustaining technologies for elderly people and maximization of the potential good these technologies can bring will require the creativity and cooperation of philosophically and professionally diverse factions.

The first pair of issues and accompanying options addresses research needs that relate to all of the subsequent issues. These include statistical data for improved health care planning and delivery and basic research to expand the scientific knowledge base. The next pair of issues and options addresses the concern of the requesting congressional committees about access to life-sustaining treatments and how access is affected by age, availability of reimbursement, and setting. The third issue area addresses what Congress might do to reduce problems in individual decisionmaking about the use of life-sustaining treatments. The two final issues and options address questions that arose in the course of this assessment about the safety and efficacy of life-sustaining technologies and the quality of care provided for elderly people once a decision has been made to provide, withhold, or withdraw life-sustaining technologies.

Associated with each policy issue are several options for congressional action, including in each case, no action. The order in which the options are presented should not imply their priority. The options are, for the most part, not mutually exclusive. In fact, a careful combination of options might produce the most desirable effects. Further, while these issues address life-sustaining treatment for elderly persons, many of them are applicable to patients of all ages.

The issues and options presented here are realistic foci for congressional oversight and legislative activity. Numerous other issues fall more appropriately within the activities of nongovernmental bodies. Ultimately, resolution of the various problems associated with the use of life-sustaining technologies for elderly people and maximization of the potential good these technologies can bring will require the creativity and cooperation of philosophically and professionally diverse factions.

Research

Issue 1: What could Congress do to strengthen and expand the statistical database on the utilization and costs of life-sustaining technologies?

1.1 Take no action.

1.2 Provide funds and instruct HCFA to conduct studies on the utilization of and expenditures for life-sustaining technologies in hospitals, nursing homes, and home care.

1.3 Instruct HCFA, the National Center for Health Statistics, and the Veterans Administration (VA) to develop and employ standardized methods for calculating and reporting utilization and costs of life-sustaining technologies.

Several factors argue against a Federal role in the collection of additional health statistics and/or establishment of a databank on the use of life-sustaining technologies. First, inaction at the Federal level (i.e., Option 1.1) would avoid the expenditures related to new data collection efforts. Additional medical recordkeeping and changes in reporting methods might be opposed by the institutions and individuals who are asked to provide the data. In addition, some observers fear that a recordkeeping system that specifies cost and reimbursement for particular technologies could lead to inappropriate economic pressures to alter treatment patterns.

On the other hand, a major finding of this assessment is that neither the magnitude of current problems nor predictions of future demand can be adequately estimated with existing data sources. (The scarcity and unreliability of available data are substantial for young as well as elderly patients.) Data on the utilization of and expenditures for life-sustaining technologies come mainly from small case studies whose results cannot be aggregated or generalized. The notable exception is dialysis, for which good utilization and expenditure data are *now* maintained, but for which the absence of data prior to Medicare coverage contributed to gross underestimates of the eventual demand for this treatment. Improved data would help inform public policy and, to the extent that the necessary recordkeeping makes clinical decisions more explicit, could also improve decisionmaking in individual cases.

Sample surveys of Medicare patients and elderly Medicaid patients who receive life-sustaining technologies (Option 1.2) would be a relatively easy and relatively inexpensive way to expand the statistical database on utilization and Federal expenditures. Careful consideration must be given to determining which life-sustaining technologies warrant this attention. At a minimum, for each selected technology, the studies should provide data on: the patient's age, diagnoses, treatment settings, clinical outcome, discharge status, and payments by Medicare and/or Medicaid. Information on expenditures by private insurers, patients, and any unpaid charges would also be desirable, to complete the cost picture. Parallel data on elderly patients in hospitals, nursing homes, and in their own homes would provide a rather comprehensive data set useful for a variety of analyses. Ideally, the data would permit cross-sectional or longitudinal analysis, comparisons among subgroups within the elderly population, and comparisons of utilization and costs in different settings. Improved information about the current situation would be essential input to any Federal policy decisions about limiting or expanding health care services, payment, or training. If maintained continuously or updated periodically, these data could be the foundation for predictions of future demand for and cost of providing particular technologies. The arguments against Option 1.2 are the same as those in support of Option 1.1.

Option 1.3 addresses the noncomparability of utilization and cost data that are currently available. Problems in utilization data result from different definitions of such terms as "chronic" or "prolonged" use, dissimilar age categories, and variations in codes for the pertinent medical and surgical procedures. "Cost" data sometimes represent charges, sometimes expenditures, and exactly what is included is seldom specified. The main argument against this approach is that the definitions and methods developed may not adequately fit the diverse needs of potential users. To reduce this possibility, standardized definitions of utilization and costs should be developed with input from all interested parties—especially hospitals, insurers, patients, health economists, and policymakers.

Issue 2: What could Congress do to strengthen and expand scientific and clinical knowledge related to the use of life-sustaining technologies, especially for elderly people?

2.1 Take no action.

2.2 Authorize and appropriate funds administered through the National Institute on Aging (NIA) for studies of life-threatening conditions in the elderly and the physiological and psychological responses of elderly patients to alternative treatments.

2.3 Provide research funds administered through NIA to coordinate work on the development of measures that better reflect the health status and reserve capacity of elderly people than does chronological age.

2.4 Authorize and appropriate funds through the Department of Health and Human Services (DHHS) or NIH to develop and test patient classification systems and other aids to clinical decisionmaking.

2.5 Authorize and appropriate funds to support an NIH research planning conference focused on the care of elderly persons with life-threatening conditions.

Option 2.1 assumes that existing Federal support for technology assessment and basic research related to life-sustaining technologies is adequate and appropriately directed, that adequate non-Federal support is available, or that additional research would not reduce problems related to the use of life-sustaining technologies. Proponents of additional research argue that little research has been focused on these topics and that information is needed to reduce inappropriate and ineffective utilization of life-sustaining technologies. Research would require additional Federal expenditures or shifting of funds from other areas. However, potential benefits, in terms of improved patient selection and improved quality of care, as well as potential reductions in the cost of care that is provided, might outweigh the costs associated with research.

Very little research has focused on the relationship between advanced age and the clinical outcomes of life-sustaining technologies. The resulting information gaps contribute to clinical uncertainty and prognostic errors, as well as suboptimal care and poor outcomes. Added Federal support for research on these topics (Option 2.2), especially prospective and longitudinal studies, could lead to improved understanding of the factors associated with different clinical outcomes, including longevity. This knowledge could lead to the development of age-indicated modifications in treatment that could, in turn, lead to increased survival of elderly persons with life-threatening conditions, with improved functional capacity, reduced complications, and less recidivism.

It has been well established that physiological changes occur at different rates and to different extents in different people, with the effect that individuals are *increasingly dissimilar* as they age. While many physicians now recognize that chronological age masks this heterogeneity, age remains the simplest single indicator of physiological status. Basic research on age-related physiological change and response to stress, directed toward the development of alternative measures of health status and reserve capacity (Option 2.3) might lead to improved accuracy in patient assessment and prognosis.

Option 2.4 proposes Federal support for the continuing development and testing of patient classification systems and other aids to clinical decisionmaking. Some of these systems, currently experimental, show considerable promise for identifying patients who are likely to benefit from treatment and patients who are likely to die despite treatment. Refinement of these systems and/or development of new approaches could reduce ineffective use of life-sustaining technologies.

Another approach to providing information that could potentially improve decisionmaking would be sponsorship of an NIH research planning conference, as suggested in Option 2.5. The conference would bring together experts in geriatrics and in critical care, medical decisionmaking, health services, and health law, with the goal of specifying and prioritizing areas of research on the care of the life-threatened elderly. A consensus about key issues would direct Federal funding to the most fruitful areas, and the visibility of such a conference could also help to stimulate private funding for identified priority areas.

Access to Care

Issue 3: What could Congress do to protect elderly persons from possible age-based discrimination in access to life-sustaining medical treatments?

3.1 Take no action.

3.2 Provide funds and instruct HCFA to conduct studies of hospital and nursing home practices regarding the offering of life-sustaining technologies to elderly patients.

3.3 Instruct HCFA to expand Medicare reimbursement for life-sustaining medical care.

(Also see Options 2.3, 5.3, and 6.4.)

Whether or not Federal action to prevent possible discrimination is warranted at this time depends on one's evaluation of the current situation. One goal of recent public policy is to protect the equal rights of all citizens, without regard to race, sex, or *age*. Ensuring equal access to needed health care is one of the responsibilities of policymakers. However, because health care resources are not unlimited and because aging is universal, "equal" access can include different interpretations of the kinds of care that must be offered, under what circumstances, and for how long. Some people argue that Medicare, because it provides health care mainly to elderly persons, is itself inequitable. On the other hand, anecdotes about limited care for hospitalized Medicare patients have stirred public concern and congressional attention. The extent to which elderly persons might be denied access to life-sustaining technologies because of their age is not known; however, limited Medicare hospital reimbursement, health professionals' ignorance of the good prognosis for many elderly patients, and residual ageism create considerable potential for age discrimination in access to these treatments.

Studies proposed in Option 3.2 would provide information about the extent to which Medicare patients and elderly Medicaid patients are offered various life-sustaining technologies in hospitals and nursing homes. This information would enable peer review organizations (PROs)[6] or other overseers to identify cases in which life-sustaining technologies were not accessible. It would not, however, be possible to draw from this conclusions about age-based discrimination unless comparable information were available for younger patients as well. Requiring sampled providers to keep records of all treatments offered to patients would benefit those patients by encouraging physicians to entertain and to discuss with patients all reasonable treatment options.

Current cost-containment pressures and limited Medicare reimbursement provide hospitals and physicians financial disincentives to admit and to aggressively treat Medicare patients whose costs are likely to exceed what Medicare will pay under PPS. Option 3.3 would remove or reduce those financial disincentives. Adjustments could be made in the level of reimbursement for DRG categories that frequently involve life-sustaining technologies, by creating new technology-specific reimbursement categories, by adding a severity of illness measure to all DRGs, by increasing the age adjustment factor that already applies to some DRGs or by raising outlier rates. Such actions would be expensive and difficult to justify when there is no proof that age-based discrimination is a serious problem. However, some people would view the protection of access to health care as important enough to justify a preventive approach.

Option 2.3 would reduce opportunities for treatment decisions based on unjustifiable generalizations about old age. Options 5.3 and 6.4 would educate patients and providers, respectively, to be better advocates for themselves and for their elderly patients.

Issue 4: What could Congress do to increase the availability of life-sustaining technologies in nonhospital settings?

4.1 Take no action.

4.2 Instruct HCFA to provide Medicare coverage for life-sustaining antibiotic therapy and short-term nutritional support outside the hospital setting.

4.3 Instruct HCFA to increase Medicare home health care coverage for personnel who provide needed services for Medicare patients dependent on life-sustaining technologies in their own homes.

4.4 Instruct HCFA to encourage the States to raise Medicaid reimbursement available to nursing homes that hire highly skilled personnel in order to provide life-sustaining technologies.

4.5 Authorize and appropriate funds to DHHS for the support of research and demonstration projects regarding the use of life-sustaining technologies in nonhospital settings.

Current medical practice and reimbursement policy favor the use of hospitals, and often their ICUs, for application of most of the life-sustaining technologies OTA studied. For patients who are medically stable and who no longer require the resources of a hospital, care in another setting is generally less costly and facilitates a less restricted lifestyle. Therefore, most people think it would be beneficial for patients, as well as more efficient, if utilization of life-sustaining technologies were shifted as much as possible to nonhospital settings (Option 4.1). Expanded availability of life-sustaining technologies outside of hospitals could, however, lead to inappropriate use, with consequent increased cost. Further, the quality of care could be jeopardized in these relatively unsupervised settings.

OTA found that some patients who could safely be treated in alternate settings are confined to hospitals because of inability to pay for services elsewhere. For some technologies, e.g., ventilation, the problem is that the unreimbursed portion of care, while it may be a small percentage of the total cost, is often still very high. For two of the technologies discussed in this assessment, life-sustaining antibiotic therapy and short-term nutritional support, Medicare reimbursement outside the hospital is completely unavailable. Option 4.2 suggests expansion of Medicare benefits to cover these technologies. Option 4.3 goes a step farther, proposing Medicare reimbursement for the personnel needed to provide any life-sustaining treatments outside of hospitals. Among these personnel are health professionals (e.g., respiratory therapists, professional nurses), and nonprofessionals (aides).

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[6] The function of PROs is to review the appropriateness of hospital admission for Medicare patients, approve payment, and monitor quality of care. On appeal, PROs also review individual cases in which admission or payment is thought to be inappropriately denied, and cases in which discharge is thought to be premature.

Option 4.4 addresses the current difficulty in nursing homes of hiring staff who have the necessary skills and credentials to provide complex care. Most nursing homes do not admit patients who are receiving mechanical ventilation, intravenous antibiotics, or TPN, and most are not equipped to provide these treatments to residents who need them. Inadequate and unpredictable reimbursement make it difficult for nursing homes to develop staff and services and, thus, limit out-of-hospital options for persons who are medically ready to be discharged from hospitals. Some nursing homes that do provide care for technology-dependent persons have negotiated special reimbursement arrangements with Medicare or Medicaid on a patient-by-patient basis. For patients who are eligible for Medicare nursing home benefits, coverage could be extended beyond the current 100-day limit. For technology-dependent Medicaid patients in nursing homes, HCFA could offer States incentives to increase reimbursement.

Information regarding the relative benefits and problems in providing life-sustaining technologies in alternative settings is piecemeal and largely anecdotal. Option 4.5 would support research and demonstration projects to clarify the types of patients for whom alternatives to the hospital (and, within hospitals, alternatives to the ICU) are safe, economical, and contribute to the patient's quality of life. Such projects could also provide information regarding the supportive services patients need in different settings, alternative methods for providing them, and the relative costs and benefits. One possible site for such projects is the teaching nursing home. An important component of such programs would be their educational benefits, i.e., through the opportunity to train health professionals within the institutions where projects go on and the dissemination of results to health professionals in other institutions.

A main argument against Options 4.2 through 4.5 is that liberalization of reimbursement for home care and nursing home care of technology-dependent patients might create substantial new demand for services and attendant new costs to the Federal Government. In addition, some people fear that quality of care cannot be assured outside the hospital. Other difficulties relate to decisions about whether coverage should be for all life-sustaining technologies or only designated ones (i.e., Option 4.2), which personnel should be reimbursed for which services (Option 4.3), and whether particular treatment settings, rather than all nonhospital settings, are to be equally encouraged.

Decisionmaking

Issue 5: What could Congress do to protect the rights of elderly patients in decisions about the use of life-sustaining interventions?

5.1 *Take no action.*

5.2 *Authorize and appropriate funds for research and demonstration projects that will provide information about current decisionmaking practices, problems, and possible solutions.*

5.3 *Support education of the public regarding their rights as patients and mechanisms for implementing these rights.*

5.4 *Instruct HCFA, the VA, and the Department of Defense to require Federal health care facilities and health care facilities that are certified to treat Medicare and Medicaid patients to: 1) record in a patient's record any advance directive the patient presents, and 2) honor that directive.*

5.5 Instruct HCFA, the VA, and the Department of Defense to require health care institutions that receive Medicare and Medicaid reimbursements as well as all Federal health care institutions to: 1) develop written policies describing the procedures they will follow in making a decision about life-sustaining technologies, and 2) communicate these policies to all patients.

5.6 Develop Federal legislation regarding advance directives and procedures for the identification of surrogate decisionmakers.

(Also see Option 6.4.)

The proper role of the Federal Government in health care decisionmaking is very controversial, with opinions ranging from *no* role to a direct, *intimate* role (as in the original "Baby Doe" regulations). Governmental involvement in the substance of treatment decisions for the life-threatened elderly would meet strong opposition from health professionals and from patients of all persuasions. More widely accepted roles for Government would focus on either the provision of information (Option 5.2 and 5.3), the establishment and protection of decisionmaking procedures (Option 5.4 through 5.6), or both. However, some people oppose all forms of governmental involvement, arguing that decisionmaking procedures as well as substantive decisions are the responsibility of qualified health care professionals (Option 5.1).

OTA's findings suggest several kinds of information about decisionmaking that could help reduce current problems. Option 5.2 calls for the collection and analysis of descriptive information about how decisions are made with regard to the use of life-sustaining technologies for elderly people. This kind of research would provide evidence on the extent to which elderly persons participate in decisions about the use of life-sustaining treatments, identify the reasons patients' wishes are not always implemented, and would identify any subgroups of the elderly population (e.g., extremely old persons, demented persons, nursing home residents) whose rights may need greater protection. Such research would also contribute to determining the practical strengths and weaknesses of different kinds of advance directives and different decisionmaking processes. However, some people might perceive this kind of research as an invasion of privacy.

Option 5.3 addresses the current scarcity of public education regarding patients' rights, the importance of making known one's wishes regarding life-sustaining treatments, and available mechanisms for formalizing these wishes. This option assumes that such education would result in more people preparing some type of formal advance directive (e.g., living will or durable power of attorney) or, at least, discussing with their family or physician their personal views regarding life-sustaining treatment. Increasing the number of persons whose wishes are known should result in an increase in the number of patients whose wishes are honored. Some people have suggested that having a clear directive from the patient is the single best way to reduce unnecessary health care expenditures. Opposition to such educational efforts might come from those who fear that the educators would advocate particular positions.

Options 5.4 and 5.5 reflect OTA's finding that, in many institutions, the approach to decisionmaking about the use of life-sustaining technologies is ad hoc. In most hospitals and nursing homes, there is no mechanism for determining or registering a patient's treatment preferences before the need for a life-sustaining technology arises, when it may not be possible to consult the patient. In some cases, health care providers are not aware that a patient who is decisionally incapable has an advance directive. Even if they are aware of the advance directive, they do not always follow it.

Formal institutional policies for decisionmaking could help protect a patient's right to participate in treatment decisions and clarify the roles and responsibilities of other participants in the decision (e.g., families, ethics committees). Institutional policies would not necessarily offer any legal protection to patients, institutions, or individual caregivers, but they could potentially acquire considerable authority as they evolve into standards of practice.

The Federal Government could require health care institutions that receive Medicare and Medicaid reimbursements and Federal health care institutions to develop formal institutional policies for decisionmaking (Option 5.5). Although many parties favor the establishment of policies for decisionmaking at the institutional level, it is not clear whether such policies should be required by the Federal Government. The number of hospitals, nursing homes, and other health care facilities that have formal institutional policies for decisionmaking appears to be growing. The recently announced JCAH requirement that hospitals and nursing homes must have a policy for decisions about resuscitation in order to be accredited by JCAH is expected to further this trend. Thus, some people believe that there is no need for a Federal requirement for institutional policies for decisionmaking. Other people believe that a Federal requirement is needed to ensure that most, if not all, health care facilities have such policies in place.

Even if the Federal Government were to require health care institutions to have policies for decisionmaking, it is unclear whether the requirement should address the content of those policies or whether the content of the required policies should be left to the discretion of each institution. If agreement is reached that content should be addressed by the Federal Government, it is unclear whether the requirement should specify questions the policies must answer (e.g., how a patient's decisionmaking capacity will be assessed or how a surrogate will be selected) or decisionmaking procedures that should be followed. Some people believe that the content of decisionmaking policies should be determined by individual institutions because of differences in their purposes, practice environments, and patient populations. Others believe that at least minimum standards should be included to protect patients' rights and ensure some consistency across jurisdictions and institutions. Selection of such standards would be difficult because of disagreement about appropriate decisionmaking practices.[7]

Option 5.6 suggests Federal legislation to authorize advance directives (living wills and durable powers of attorney for health care) and to specify procedures for identifying surrogate decisionmakers for patients who are not decisionally capable and who have no advance directive. Federal legislation to authorize advance directives would make these methods of documenting an individual's treatment preferences available to all Americans, including those who live in States that have not enacted statutes allowing advance directives. Federal legislation could ensure that a living will or durable power of attorney for health care executed in one State would be accepted in other States. Proponents of advance directives, who view them as an important safeguard of patient autonomy, would probably welcome such legislation. Yet disagreement about specific provisions of advance directives, e.g., whether they should allow withholding or withdrawal of life-sustaining nutrition, hydration, and medications and whether they should allow withholding or withdrawal of treatment from persons who are not terminally ill, would complicate the development and enactment of such legislation.

People who believe that life should be sustained whenever it is technically possible to do so would probably oppose Federal legislation authorizing advance directives because the directives usually allow withholding or withdrawal of treatment. Some people would also object to Federal legislation in an area that has traditionally been governed by the States and might prefer Federal actions that encourage States to enact statutes authorizing advance directives. Others might prefer that the Federal role be limited to support of public education about advance directives (Option 5.3).

Federal legislation specifying procedures for identifying a surrogate decisionmaker for patients who are decisionally incapable and have no advance directive and defining the role and responsibilities of the surrogate could reduce confusion about the legality of existing decisionmaking practices for these patients. Such legislation might be modeled after the family consent laws now in effect in 15 States. Alternatively, the Federal Government could require health care instititutions to have formal policies defining procedures for surrogate decisionmaking as a part of the institution's policy for decisionmaking, as in Option 5.5. Objections to these approaches are similar to objections to Option 5.5.

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[7] As a follow-on to this assessment, OTA has commissioned a report on institutional policies for decisionmaking that will consider these questions in more detail. That report will be available in early 1988.

Quality of Care

Issue 6: What could Congress do to improve the quality of care associated with the use of life-sustaining technologies for elderly people?

6.1 Take no action.

6.2 Instruct the Federal agencies engaged in technology assessment and clinical trials, i.e., the National Center for Health Services Research and Health Care Technology Assessment's Office of Health Technology Assessment (OHTA), the Food and Drug Administration (FDA), NIH, and OTA to make studies of life-sustaining technologies a priority.

6.3 Provide Federal funds or tax incentives for research and development of improved life-sustaining technologies (equipment and products), including refinements that simplify operation and maintenance.

6.4 Authorize and appropriate funds to DHHS and the VA to support education and training as well as special practice models for health professionals who care for the life-threatened elderly.

6.5 Authorize and appropriate funds for DHHS to develop model programs offering comprehensive support services to technology-dependent elderly persons who need them.

This assessment has raised both general questions about efficacy and safety of some life-sustaining technologies and questions that are specific to the use of these technologies for elderly patients. Problems arise from deficits in the knowledge base, the technologies, and the personnel. Numerous activities that have potential benefits in terms of ensuring the efficacy and safety of life-sustaining technologies for elderly patients are already underway. These include the regular activities of FDA, technology assessments by OTA and OHTA, clinical studies by NIH, and support for health professions training, including programs to expand education and training in geriatrics and gerontology. Some would conclude that these activities are adequate. However, with respect to special needs of the life-threatened elderly, none of these programs goes very far.

Questions have been raised about the reliability of some equipment and products and about undue complexity (and, therefore, cost) of others. These questions suggest the need for assessment of life-sustaining technologies in addition to those OTA has studied and for correction of identified problems. Option 6.2 would provide information about any problems related to particular medical technologies used to sustain life. This would inform policy decisions about whether or not a particular technology ought to be widely available, or reimbursed, and clinical decisions about its use for individual patients. A practical drawback to Option 6.2 is that there are a large number of life-sustaining technologies, and new ones being developed, and only a fraction of them can be assessed. Also, unless tied to approval by FDA or to reimbursement decisions, the results of these assessments might have little effect. Option 6.3 would encourage R&D in Federal laboratories, provide grants to universities and major medical centers, and support special incentives to the private sector to improve existing technologies and to develop reliable and relatively simple technologies suitable for use in the home or nursing home.

Option 6.4 would support curriculum development, instruction, and practice models focused on: 1) geriatrics and gerontology, and 2) humanistic care of the dying, in order to simultaneously increase the supply and upgrade the capabilities of pertinent health professionals. Programs would target physicians, nurses, and allied health professionals still in training as well as health professionals already in practice.

The Federal Government currently supports education and training in geriatrics and gerontology through programs of the NIA, National Institute of Mental Health, Administration on Aging, Health Resources and Services Administration (HRSA), and the VA. Despite dramatic increases in the numbers of physicians and other health professionals committed to geriatrics, serious manpower shortages and barriers to recruitment suggest that more needs to be done. Moreover, existing education and training does little to specifically prepare physicians or nurses to care for elderly persons who become candidates for life-sustaining technologies. Pertinent curricular innovations, e.g., clinical ethics, death and dying, health law, decision analysis, assessment of patients' decision-making capacity, and interdisciplinary teamwork are relatively new and, under current cost-containment strategies, their continuance is threatened. There is no cross-training between specialists in geriatrics and specialists in critical care. Many people assume that providing more education and training in these areas would improve the quality of care for the life-threatened elderly. There has been, however, very little research to evaluate the benefits of this kind of education, and, therefore, limited evidence that such programs have a significant effect on treatment outcomes.

Option 6.5 recognizes that many patients who are chronically dependent on a life-sustaining technology have unmet needs for financial and other kinds of assistance, such as attendants, transportation, special equipment, architectural modifications, group purchasing of medical supplies, etc. New Federal programs that target specific groups of patients for special benefits could be criticized as perpetuating a disjointed approach to health care, and new expenditures would be required. In France and England, comprehensive programs for ventilator-dependent patients have proved to be cost-effective and of great benefit to patients, enabling some technology-dependent persons to live in their own homes, with relative independence and maximum quality of life.

Issue 7: What could Congress do to improve the quality of care for people from whom life-sustaining treatments are withheld or withdrawn?

7.1 Take no action.

7.2 Instruct HCFA to extend eligibility criteria for hospice care and palliative treatments, to make them more widely available.

7.3 Appropriate funds and direct NIH or HRSA to support research and training to study the dying process and to develop methods of palliative care for patients from whom life-sustaining technologies have been withheld or withdrawn.

Federal involvement in research, health professions education, and reimbursement for health care have greatly benefited patients who want aggressive medical treatment. Good care has been widely available and the financial barriers largely removed. However, for patients from whom life-sustaining technologies are withheld or withdrawn, treatment options are undeveloped, and resources are scarce. The single focus of Federal efforts on behalf of these patients is hospice care and the provision of limited hospice benefits under Medicare.

The hospice model of care was developed to meet the physiological and psychological needs of patients who have been diagnosed as terminally ill and who choose to forgo aggressive treatment. Most hospice patients are victims of incurable cancers who consciously requested this kind of care. Hospice care has not been available in this country to persons who cannot make decisions about their care and those who have not been designated terminally ill. The potential benefits for some such patients, for example, severely demented patients who cannot be dialyzed, decisionally capable ESRD patients who choose to discontinue dialysis, and patients with chronic obstructive pulmonary disease who refuse mechanical ventilation, have not been studied. Option 7.2 would make hospice care more widely available.

Anecdotal evidence suggests that, following a decision to withhold or withdraw life-sustaining technologies, patients are sometimes essentially abandoned. Health professionals may simply have nothing to offer these patients. Therapeutic options are exhausted or rejected; methods and resources for pain control and bereavement counseling are undiscovered, illegal, or unfunded. Option 7.3 is to support behavioral, pharmacological, and health services research geared toward discovering and then meeting the needs of this group of patients. For these people, Option 7.3 would provide some answers about the potential benefits of existing forms of hospice care, develop options to the use of life-sustaining technologies, and then train health care professionals in these methods. The cost of such programs might be returned many times by reduced expenditures for life-sustaining technologies. Of all the many research needs identified in this assessment, those referred to in Option 7.3 are among the most important.

Chapter 2

The Context of the Report

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Chapter 2

The Context of the Report

INTRODUCTION

This chapter provides an overview of the technological developments, treatment settings, public attitudes and opinions, government policies, and demographic changes that are the historical and societal context for this OTA report. The chapter presents background information that is common to the other chapters and is the basis for the congressional concerns that led to the assessment. None of the topics is analyzed in detail, although each could be the focus of a full assessment.

In the early 1900s, there were few effective treatments for life-threatening diseases. Medical care consisted primarily of palliative treatments derived from clinical experience and intuition and intended to mitigate the effects of diseases that were considered natural and inevitable. Since then, advances in biomedical science and technology have produced effective treatments for some diseases, enabling doctors to keep people alive who would certainly have died previously. The use of these treatments, particularly antibiotics, has altered life expectancy and the age distribution of our population. The availability of the treatments has had far-reaching effects on medical practice and on attitudes and expectations about illness, death, and dying.

In part because of the availability of increasingly complex medical treatments, more people are treated in hospitals now than 50 years ago, and more die there. More physicians, nurses, and other health care professionals are involved in the care of each patient and are thus aware of and potentially involved in treatment decisions. More people are cared for in nursing homes and by home health agencies and outpatient clinics than ever before, and more health care professionals and others in these multiperson settings are aware of and potentially involved in life-and-death decisions for these patients. Thus, decisions that would once have been made privately by an individual physician, who might or might not have consulted with the patient or family, are now made in the view of many different people who have diverse opinions and beliefs about the decision and the decisionmaking process.

The inherent difficulty of life-and-death decisions involving medical technologies and the increasingly public nature of the decisionmaking process have led to intense clinical, legal, and ethical debate; to court cases that define the rights of patients to refuse treatment and the role of families, physicians, and health care institutions in the decisionmaking process; to State legislation on advance directives and surrogate decisionmaking; and to the formulation of guidelines for decisionmaking by government-appointed task forces and commissions, professional associations, citizens groups, and others. Much of this debate and the relevant court cases, legislation, and guidelines address questions about possible overtreatment and about appropriate procedures for deciding whether or when life-sustaining treatment should be withheld or withdrawn.

Concurrently, rising health care costs and expenditures have generated widespread public concern and have led to changes in medical practices and in private insurance and public programs that pay for medical care—changes intended to limit health care costs and spending. The pressure for cost containment has added another dimension to the debate about life-sustaining technologies.

In the past, a decision to use or withhold a life-sustaining treatment for an individual patient was based on consideration of the patient's physical condition, legal and ethical constraints, and, in some cases, the wishes of the patient and family. The cost of medical care has always been a consideration for patients who are uninsured, but most people, particularly elderly people, are insured, and most are covered for life-sustaining treatments (although sometimes only when the treatments are provided in a hospital). Thus, elderly patients, their families, and physicians have generally been insulated from cost considerations with regard to life-sustaining treatments. Since about 95 percent of elderly people are covered by Medicare, and some are also eligible for Medicaid, Veterans Administration (VA), or other publicly funded programs, the cost of life-sustaining treatments for them has been primarily a public cost.

Some ethicists have theorized about the relationship between individual treatment decisions and allocation of scarce resources on a societal level (see ch. 4). Likewise, government-appointed task forces and commissions that have issued guidelines for decisionmaking have concluded that health care institutions and individual clinicians can justifiably limit certain treatment options on an institutional basis in order to allocate scarce resources more equitably (136,153). In the past, however, the public cost of care has generally not been a factor in individual treatment decisions. Nor have the courts that have ruled on cases involving withholding and withdrawal of life-sustaining treatment recognized the public cost of the treatment as a valid consideration in individual treatment decisions.

Recent changes in Medicare and other public programs have created institutional pressures on physicians and other health care professionals to reduce costs and thus have introduced consideration of the public cost of care into individual treatment decisions on a wide scale. These changes have led to new concerns about possible undertreatment and limitations on access to appropriate care—concerns that are superimposed on the unresolved questions about possible overtreatment and about procedures for deciding whether or when life-sustaining treatment should be withheld or withdrawn.

Along with the increased awareness and alarm about health care costs and expenditures, there is a growing recognition among government officials, policy analysts, and the public of the growth of the elderly population, both in absolute numbers and as a proportion of the whole population. Elderly people are more likely to experience life-threatening illnesses than younger people. Health care costs are generally higher for elderly than for younger people, and a significant percentage of the medical care of elderly people is publicly funded. Finally, since elderly people are the primary group covered by Medicare, they are also the group affected by changes in Medicare policies. These factors and others discussed in this chapter have focused public attention and congressional concern on the use of life-sustaining technologies for the elderly.

CHANGING TECHNOLOGY

Advances in life-sustaining medical technology during this century have built on knowledge accumulated during preceding centuries, but the pace of discovery and technological change in recent decades is unprecedented. Major advances began in the 1920s with the isolation of insulin for treatment of diabetes, the invention of the first mechanical ventilator (the "iron lung"), and the discovery of penicillin. Sulfa drugs were first used in the 1930s. The first artificial kidney was used during World War II, although long-term kidney dialysis was not possible until the 1960s.

The 1950s saw the first open-heart surgery, discovery of the polio vaccine, and rapid development of mechanical ventilators. The first intensive care units (ICUs) were established in this period.

In the 1960s, cardiopulmonary resuscitation (CPR), coronary artery bypass surgery, kidney transplants, total parenteral nutrition, and radiotherapy and chemotherapy for cancer were introduced. Coronary care units (CCUs) were established. The first heart transplant occurred in 1967.

The 1970s brought continued progress in the treatment of cancer, heart disease, heart attack, and stroke. With the introduction of the drug cyclosporine in 1979, the biggest obstacle to successful transplantation—immunological rejection—was reduced. The first liver transplant occurred in the 1970s, and heart and kidney transplants became more common. In 1985, about 600 people received liver transplants; 700 received heart transplants; and about 8,000 received kidney transplants (30). In 1982, an artificial heart was placed in a living patient for the first time.

The pace of technological change is increasing. Although it is impossible to predict the next breakthrough, new technologies to treat life-threatening diseases are constantly being developed. In 1984-85, OTA polled academic researchers, trade associations, medical device companies, and government analysts to identify medical technologies likely to appear in the next 5 to 15 years. Responses to the poll indicate that future developments in life-sustaining treatments may occur in the areas of artificial organs and transplanted organs and tissues; cancer vaccines; implantable drug delivery systems for cancer and other diseases; and immunosuppressive drugs. Improvements in medical imaging and other diagnostic and information technologies are expected to improve diagnostic accuracy and medical decisionmaking (201).

Some analysts say that we now have, or will soon have, the capability to maintain biological existence indefinitely (55). Others say that the timing of death—once a matter of fate—is now a matter of human choice (132,136,153).

Technology Development and Diffusion

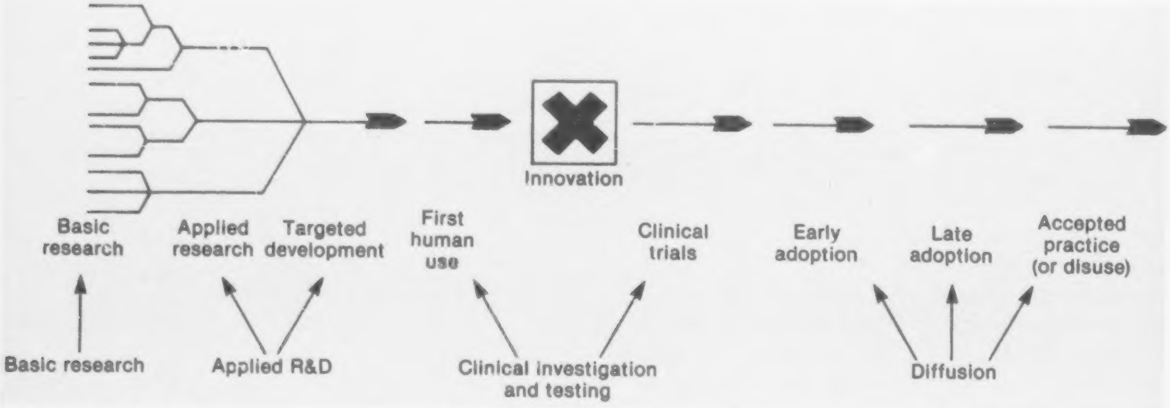
New medical technologies, including life-sustaining technologies, are developed as an outgrowth of basic biomedical and applied research and targeted development (see fig. 2-1). Some are made possible by engineering breakthroughs that allow, for example, miniaturization of devices or the use of a new power source.

The Federal Government pays for about half of all health-related research and development. Basic biomedical research is supported primarily by the National Institutes of Health (NIH), but other agencies of the Department of Health and Human Services (DHHS), the Department of Defense, the Department of Energy, the VA, and other Federal agencies also fund health-related research (231).

Private industry and nonprofit organizations pay for the other half of health-related research and development. Most applied research and targeted development is supported by private industry (199). Nonprofit organizations, such as the American Heart Association and the American Cancer Society, fund both basic and applied biomedical research.

Since the Federal Government pays for such a large proportion of health-related research, funding decisions by Federal agencies influence the direction of research and the areas in which development of new technologies is most likely. Massive Federal funding for research on heart disease in the 1960s and 1970s, for example, was an important factor in the subsequent development of new technologies for treatment of cardiovascular disease.

Figure 2-1.—Technology Development and Diffusion



SOURCE: U.S. [illegible], Office of Technology Assessment, *Development of Medical Technology: Opportunities for Assessment* (Washington, DC: U.S. Government Printing Office, 1976).

Diffusion of new technologies into the health care system results from decisions to adopt a technology by physicians, hospital administrators, and others and decisions to use the technology by physicians and, to some extent, patients and their families. Whether reimbursement for the technology is available obviously affects these decisions (37,199). Since about 90 percent of hospital care for persons of all ages is paid by private insurance and public programs, the coverage and reimbursement policies of private insurance and public programs strongly influence which technologies are adopted and used in hospitals. Medicare pays for about three-quarters of the hospital care of elderly people. The remaining one-quarter is divided about evenly between other public programs, primarily Medicaid and the VA, and private sources, including private insurance and direct payments by individuals (205). As a result, Medicare policies and the policies of other public programs and private insurers influence which technologies are adopted and used for elderly people (199,200).

Until recently, Medicare, most other public programs, and private insurers reimbursed hospitals on the basis of costs they incurred in treating patients. Cost-based reimbursement generally encouraged the use of medical technologies. Medicare's Part A prospective payment system (PPS), introduced in 1983, reimburses hospitals at a fixed rate per case, based primarily on the patient's diagnosis. PPS, which is discussed at greater length later in this chapter, is expected to encourage adoption and use of technologies that reduce costs and length of stay, and discourage adoption and use of technologies that increase costs and length of stay (199,200).

Public programs and private insurance generally pay for a smaller percentage of health care expenditures in outpatient clinics, nursing homes, and in the patient's home than in hospitals. Nevertheless, the coverage and reimbursement policies of public programs and private insurers are important determinants of the adoption and use of medical technologies, especially very costly technologies, in these settings. For elderly people, Medicare coverage and reimbursement policies are most important.

The methods used by public programs and private insurance to pay for physician services also affect adoption and use of medical technologies. Medicare's current fee-for-service method of paying for physician services encourages physicians to use medical technologies because they are paid for each service performed. Similar payment methods of other public programs and private insurance also encourage adoption and use of medical technologies. Alternate methods, such as the per capita payment method used by health maintenance organizations (HMOs), may discourage adoption and use of some technologies (203).

The policies of public programs and private insurers that affect the adoption and use of medical technologies also influence the decisions of medical device and drug manufacturers about areas of research and product development. The financial incentives created by PPS, for example, are expected to encourage research and development of technologies that reduce a patient's length of stay and reduce the cost of a patient's hospitalization to the hospital.

Government Regulation, Coverage Decisions, and Technology Assessment

Drugs and medical devices are regulated by the Food and Drug Administration (FDA). Medical procedures are not regulated by FDA, but the process by which they are approved for coverage by Medicare may involve an assessment of their safety and effectiveness.

The Medical Device Amendments of 1976 that mandated FDA regulation of new medical devices defined three categories of devices based on the potential risk associated with each category (23, 200):

- Class I devices are those that generally present little risk. Manufacturers must notify FDA before such devices are marketed and must conform to good manufacturing practices in producing, packaging, storing, and installing the devices.
- Class II devices are those for which performance standards must be met, according to the

1976 legislation. Most Class II devices are now regulated as if they were Class I devices, however, because the required performance standards have not been developed.

- Class III devices are those that support life and those whose use involves a relatively high risk of illness or injury. Manufacturers are required to demonstrate the safety and effectiveness of Class III devices before they are marketed.

A 1984 OTA report on medical devices discussed the FDA regulatory process in detail and concluded that the effectiveness of the process could not be determined because of lack of reliable information about the incidence of illness, injuries, or other problems associated with the use of medical devices (199). Since then, new regulations have required manufacturers to report problems with medical devices to FDA. The Health Industry Manufacturers Association has complained that the reporting requirements are vague, thus compliance is difficult (54). Whether the requirements ensure that serious problems in the safety and effectiveness of medical devices will come to FDA's attention is unclear.

Medicare, other government programs, and private insurers generally do not cover drugs or medical devices that have not been approved by FDA. In addition, by law Medicare can only cover medical technologies that are "reasonable and necessary" for diagnosis, treatment, or improved functioning of a malformed body part. Beyond these basic requirements, which are themselves subject to varied interpretation, the criteria and procedures for determining which medical technologies will be covered by Medicare are even less clear.

Some coverage decisions are made at the national level by the Health Care Financing Administration (HCFA). Most, however, are made by Medicare intermediaries and carriers (the contractors who process Medicare claims in each geographic area). Thus, coverage decisions may vary from one region to another. Sometimes they are made on a case-by-case basis. National coverage policies have evolved primarily in response to questions from individual contractors about paying for a specific technology. HCFA decisions about coverage have limited legal or regulatory authority though, and contractors may or may not comply with them (199,200).[1]

Some Medicare coverage decisions are based on recommendations of the Office of Health Technology Assessment (OHTA) in the National Center for Health Services Research and Health Care Technology Assessment. OHTA assesses the safety and effectiveness of medical devices and procedures (127), but it evaluates only a small proportion of the thousands of new technologies introduced each year.

Some devices that FDA has approved for marketing are not recommended for Medicare coverage by OHTA, often because of a lack of demonstrated effectiveness. HCFA is not required to follow OHTA recommendations, however, and some OHTA recommendations have been overridden (37).

A recent report on technology assessment and Medicare coverage decisions (112) recommended many changes in the way that these decisions are made, including the development of a uniform national process for coverage decisions, an expanded role for OHTA in technology assessment and coverage decisions, and the establishment of a national panel of experts to assist with the evaluation of medical and cost data to determine cost-effectiveness. In April 1987, HCFA requested public comment on new procedures for making coverage decisions (62).

The Prospective Payment Assessment Commission (ProPAC), an agency established by Congress to monitor PPS, advises DHHS about adjustments in hospital reimbursement rates, including adjustments required because of technological changes. For this reason, it is charged with conducting and sponsoring medical technology assessments. Thus far, however, ProPAC has done little technology assessment, primarily because of budget limitations, and relies instead on published literature and other available information about safety and effectiveness to back up its recommendations (148).

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[1] Some medical device manufacturers believe that the arbitrary nature of Medicare procedures for determining coverage discourages private sector commitment to expensive R&D efforts on devices that might be beneficial, especially devices targeted for nonhospital settings (49).

NIH sponsors clinical trials to assess new technologies. NIH also sponsors consensus development conferences that are intended to resolve questions about the clinical application of medical technologies. A panel, including research scientists, physicians, nurses, patients, lawyers, ethicists, economists, and others, evaluates available information about a medical technology and then issues a consensus statement. Since the initiation of the consensus development process in 1977, conferences have been held on about 60 topics, including coronary artery bypass surgery (March 1981), critical care medicine (March 1983), and management of pain (May 1986). With its focus on clinical applications, the NIH consensus development process goes beyond determination of safety and effectiveness to address questions about how the technology should be used and which types of patients it will benefit.

In addition to OHTA and NIH, several States and at least 45 private groups also have medical technology assessment programs. The American Medical Association sponsors a Diagnostic and Therapeutic Technology Assessment Project, for example, and the American College of Physicians sponsors a Clinical Efficacy Assessment Project. The American Hospital Association, the Blue Cross and Blue Shield Association of America, other insurers, manufacturers, and universities also conduct medical technology assessments (37,127,148).

Despite these assessment activities, some analysts complain that new technologies are introduced into the health care system too soon, before there has been adequate evaluation of their safety, effectiveness, and appropriateness for specified applications (36,91). Other analysts suggest that the lengthy period required for assessment, approval, and coverage of new technologies may hamper timely diffusion of valuable new technologies. One recent review found that an average of 62 months elapsed between the beginning of the FDA regulatory process and final approval of new devices for marketing. OHTA assessments required an average of 26 months (37).

The Institute of Medicine recently established a Council on Health Care Technology to encourage the development and use of health care technology assessment. The new Council will serve as an information clearinghouse on technology assessment. It will identify and develop assessment criteria and methods, promote training and education in technology assessment, and coordinate and contract for technology assessments (87).

Some observers have suggested that one way of lessening the problem of allocating scarce resources on a societal level and improving individual treatment decisions is to provide physicians with more and better information about the effectiveness of specific technologies (66,91,168). This report discusses whether such information is available with regard to elderly patients and the five technologies OTA studied.

TREATMENT SETTINGS

Hospitals and Intensive Care Units

Over the past 20 to 40 years, the use of hospitals as a setting for life-sustaining treatment and as a place to die has increased. One reason for this change is that the special equipment, highly trained staff, and intensive monitoring needed by patients receiving complex medical technologies are usually only available in hospitals.

Hospital ICUs were first set up in the 1950s primarily to provide the intensive monitoring required by the large number of polio patients receiving mechanical ventilation (27). By 1958, about one-fourth of all community hospitals with more than 300 beds had an ICU. Now at least 80 percent of hospitals have an ICU (27).

Another reason for the increased use of hospitals is the financial incentives for inpatient as opposed to outpatient treatment created by the Medicare and Medicaid programs enacted in 1965. Although little information is available about the use of hospitals for life-sustaining or terminal care in the first decades of this century, and data for later periods are incomplete and frequently not comparable, it can be shown that the greatest increase in hospital use in the last year of life occurred in the mid to late 1960s, after the introduction of Medicare and Medicaid (170).

A third reason for the increased use of hospitals as a setting for care of severely and terminally ill people is that, unlike 40 to 50 years ago, many Americans today have had little direct experience taking care of a very sick or dying person. For this and other reasons, they may be unwilling or unable to care for such persons at home (51).

The shift to hospitals and other institutions as a place to die began about the time of or just after World War II. The percentage of people of all ages who die in hospitals or other institutions increased from 37 percent in 1937, to 50 percent in 1948, and 61 percent in 1961 (170). By the 1970s, more than 70 percent of all deaths occurred in hospitals or other institutions (25,108), and the percentage may be even higher now (51,73).

Among elderly people, the percentage of persons who die in hospitals decreases with age. In 1984, of all persons age 65 to 74 who died, 68 percent died in hospitals, compared to 62 percent of those age 75 to 84 who died, and about 50 percent of those over age 85 who died (217). Conversely, the percentage of persons who die in nursing homes increases with age.

The use of hospitals and ICUs for the care of severely and terminally ill people has two important implications for decisions about life-sustaining technologies. First, there is a general presumption in favor of aggressive treatment in these settings. Factors that contribute to that presumption are the availability of equipment and skilled staff in hospitals, the fact that hospitals and ICUs are established to treat illness, the attitudes and training of many physicians and other health care professionals, and the perceived vulnerability of these institutions to malpractice charges for failure to treat.

Secondly, decisionmaking is often more complex in multiperson settings than when only a single physician, patient, and family are involved. Although final authority for treatment decisions in hospitals and ICUs may rest with the patient's personal physician, the patient, and the family, many other people, including consulting and staff physicians, residents, nurses, and allied health professionals, may have information about specific patients and expertise that are relevant to treatment decisions. Representatives of the institution, including administrators and lawyers, may have both information and concerns about the impact of these decisions on the institution. Clergymen and other professional and lay counselors are also often involved.

Sometimes these other health care professionals, institutional representatives, and counselors play as great or greater roles in implementing decisions about life-sustaining treatments and responding to their effects than the patient's primary physician or family. Nurses are a good example (141, 185). According to one observer:

> The nurses do not set the course of treatment, or decide when the treatment must end. The nurses make no life-or-death choices for these patients—not publicly anyway.
>
> All the nurses do is cope with them, full time, over and over again. All the nurses do is look square in the face, longer and more directly than anybody else in medicine or the law, at the effect of decisions that other people make (70).

When the knowledge, perspectives, and values of nurses and other persons involved in the care of patients are not incorporated into the decisionmaking process, conflict may arise with regard to individual treatment decisions, professional roles, institutional policies, or all three (116,141, 187,229,232). Such conflict generates pressure for professional and institutional guidelines for decisionmaking and sometimes erupts into legal battles.

Nursing Homes

Nursing homes are a common treatment setting for severely debilitated and terminally ill elderly people, and thus a place where decisions about life-sustaining treatments are made. Use of nursing homes has increased considerably since Medicaid, and to a lesser extent Medicare, reimbursement became available. The percentage of all elderly people living in nursing homes and homes for the aged grew from less than 2 percent in 1950 to about 5 percent in 1980 (107).

Nearly one-fourth of those over age 85 are in nursing homes at any one time, and many very old people die in nursing homes. In 1978, for example, 38 percent of decedents over age 85 died in nursing homes, compared to only 9 percent of decedents age 65 to 74 and 23 percent of decedents age 75 to 84 (119).

As in hospitals and ICUs, many different people are involved in the care of nursing home residents and are thus aware of and potentially involved in treatment decisions. This situation may lead to some of the same decisionmaking problems in nursing homes as in hospitals.

Little is known about the presumption for or against life-sustaining treatment in nursing homes. Anecdotal evidence suggests that some nursing homes present themselves to residents, families, and the community as health care institutions intent on rehabilitation of their residents. Some of these facilities seek to minimize the awareness of death in the facility and prefer to transfer residents to a hospital when death seems imminent.

Other nursing homes see themselves more as a home for the resident. These facilities may prefer not to transfer severely debilitated or terminally ill residents to a hospital when death seems to be imminent and may instead emphasize supportive care in the nursing home. Even in these facilities, however, fear of legal ramifications may result in decisions to provide life-sustaining treatment for such residents, sometimes in opposition to the resident's wishes, as the following example suggests:

For several years, an elderly lady has been living alone in an apartment with homemaker services (cooking, cleaning, and laundry) provided by a local home care agency. The lady has become frail and is sometimes forgetful. Her two daughters would like to have her admitted to a nursing home where she would be safer. However, the lady does not want any aggressive medical care if she becomes seriously debilitated, and she says she definitely does not want to be tube-fed.

A social worker at the nursing home she and her daughters selected has advised them that although the facility would like to comply with the elderly lady's wishes, the staff believes that state law requires tube feeding in almost all cases when the resident is not eating, and the facility would probably have to provide it. The lady and her daughters agree that under these circumstances she is better off in the apartment for as long as she can manage, even if she is not entirely safe there.

Home Health Care

Over the past 10 years, home health care has become increasingly common, partly because of the recognition that it can be less costly than hospital or nursing home care; partly because most people prefer to remain in their own homes; and partly because technological developments now make it possible to provide many life-sustaining treatments, including mechanical ventilation, dialysis, nutritional support, and intravenous antibiotics in the home (99).

Home health care has become "big business," with estimates for all home health care products and services of $2 to $4 billion annually. Continued growth is expected as a result of PPS and other public and private cost-containment measures that are resulting in shorter hospital stays and earlier discharges (22,38,59).

Some observers fear that the involvement of private businesses and the potential for financial profit in home health care will lead to overuse of life-sustaining technologies in the home for severely debilitated or terminally ill persons who may not benefit from them. Others fear that lack of reimbursement for some life-sustaining treatments provided in the home may wrongly restrict their use. The report addresses the relationship among treatment setting, patient selection criteria, the availability of reimbursement, and the use of the five technologies OTA studied.

PERSPECTIVES ON LIFE-SUSTAINING TECHNOLOGIES AND RELATED ISSUES

New life-sustaining technologies are generally greeted with wonder and appreciation. Case histories of people whose lives they have saved are reported in the media, and the scientists, engineers, clinicians, and patients involved in their development and first use are regarded as heroes. Recognition of problems associated with the technologies or their use for certain purposes comes later.

This section reviews people's opinions, beliefs, and attitudes about life-sustaining technologies and related issues as they have been reported in the media, public opinion polls, and elsewhere. Inclusion of statements and ideas in this section does not imply their endorsement by OTA. Nor does it suggest that they are widely held, except where specific public opinion polls are cited. Likewise, the inclusion of case examples does not imply that such situations occur frequently.

When these opinions, ideas, and case examples are reported in the media, they generate public and congressional concern about life-sustaining technologies. They are cited here to describe the context of the debate about these technologies, to illustrate the diversity and intensity of opinions, and to frame the issues that are addressed in other chapters.

Opinions About Life-Sustaining Technologies

In recent years, very negative opinions have been expressed about the life-sustaining technologies discussed in this report. They are viewed by some people as needlessly prolonging the dying process, and many instances of poor outcome and patient suffering associated with their use have been reported. For example:

- One man told the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research that his 89-year-old mother's ribs were broken during a successful resuscitation attempt by a hospital emergency room team. "She never said another word, but moaned in pain the whole time. I think this was a moral abomination" (60).
- A newspaper article described an 82-year-old woman who was put on a mechanical ventilator following bypass surgery. She could not talk because of the tubes in her throat but wrote notes to her daughter, saying "Please let me die." The tubes were not removed, and when she tried to pull them out herself, her hands were strapped to the bed (122).
- Another article described a 77-year-old retired school teacher who was admitted to a hospital with end stage kidney and respiratory disease and placed on dialysis and a mechanical ventilator. After her death, her husband said that if he had known what was going to happen, he would not have brought her to the hospital. "She didn't take anything by mouth so they fed her with an N.G. (nasogastric) tube. She was constantly pulling at the tape, trying to pull it out. She pulled it out twice. They put it in a third time. It was a heart-breaking experience" (96).

Mercy killings and suicides associated with the use of life-sustaining treatments have also been reported:

- In October 1984, a comatose 84-year-old woman on a respirator in a Washington, DC, hospital was stabbed to death by her 24-year-old grandson. A newspaper report stated that the family had been "bitterly divided about whether to remove her from the machines that were keeping her alive" (126).
- A newspaper article reported one physician's observation that a surprisingly high number of dialysis patients are involved in fatal one-car crashes into bridges and abutments—deaths that are classified as accidents rather than suicides (124).

Statistics and anecdotes demonstrating positive outcomes of life-sustaining technologies are available and are cited throughout this report. Moreover, negative attitudes about life-sustaining technologies may not be related to the technologies themselves, but rather to their use and outcome for individual patients. Many people acknowledge that the same technologies that they view as unnecessarily prolonging the suffering of a relative or friend can also restore life and good or satisfactory functioning for other patients.

The negative attitudes expressed in the anecdotes suggest, however, that there may be aspects of some life-sustaining treatments that are unnecessarily painful or uncomfortable for patients. Technological improvements that might lessen patient suffering associated with the treatments could change some people's opinions about them. Aspects of each of the technologies that may be particularly burdensome are noted in the report.

Perspectives on Withholding and Withdrawing Life-Sustaining Treatment

Some people believe that the process of dying may be more fearful than death itself and that in some cases, "death is not the enemy" (102). These individuals oppose the use of life-sustaining treatments in such cases and instead advocate withholding or withdrawing treatment to allow death to occur "naturally" (19,101,111,222).

Advocacy of natural death, or "death with dignity" as it is often called, could not have existed prior to the development and widespread use of the technologies discussed in this report. At present, the movement for "death with dignity"—i.e., without machines, monitors, or tubes and without the frantic final attempts to sustain life that sometimes occur in hospitals and ICUs and to a lesser extent in other health care settings—appears to be growing. The expansion of hospice programs in this country and a growing interest in palliative or supportive care attest to the appeal of the "death with dignity" concept. Many advocates of "death with dignity" also support the concept of "the right to die"—i.e., the individual's right to refuse any treatment even if the outcome is death.

In contrast, other individuals and groups generally oppose withholding or withdrawing life-sustaining treatment except when a patient is terminally ill *and* expected to die imminently. In their view, it is morally wrong to withhold or withdraw life-sustaining treatment from patients who may be comatose, severely debilitated, or terminally ill *but are not expected to die imminently*. This position is often called "the right to life" position. Many advocates of "the right to life" and others regard withholding or withdrawal of life-sustaining treatment from patients who are not expected to die imminently as discrimination against handicapped or disabled people (52,83).

Recent growth in the movement for "death with dignity" or "the right to die" is alarming to advocates of "the right to life." They believe that implementation of the "death with dignity" concept has resulted in or will result in denial of potentially beneficial treatment, particularly for patients who are mentally retarded, confused, or unable to demand treatment for themselves for any reason. Advocates of "the right to life" also fear that "the right to die" will become a "duty to die" for elderly and handicapped people (52,83). Some individuals and groups believe that nursing home residents are particularly at risk of being denied potentially beneficial treatment as a result of "the right to die" movement and other factors (83,96).

Public opinion polls indicate that about 75 percent of the public supports the idea that life-sustaining treatments may be withheld or withdrawn in some circumstances. Survey questions have been worded differently and thus are not strictly comparable; some stress that the patient is terminally ill or that the life-sustaining treatment is futile; others emphasize that the patient and/or the family has requested withholding or withdrawal.

A 1986 American Medical Association (AMA) poll asked, for example:

> Would you favor or oppose withdrawing life support systems, including food and water, from hopelessly ill or irreversibly comatose patients if they or their families request it?

Seventy-three percent of the 1,510 respondents favored withdrawing treatment in these circumstances; 15 percent were opposed, and 12 percent were unsure (11); 75 percent of those under age 65 favored the option, compared to 64 percent of those over age 65.

Another poll asked:

> Medical technology now enables doctors to prolong the lives of many people who are terminally ill. Do you believe doctors should stop using these machines if the patient asks, even if that means the patient will die?

Seventy-seven percent of respondents answered yes; 15 percent, no; and 8 percent said they did not know. Higher income and higher education were associated with affirmative answers. Moreover, only 60 percent of blacks answered yes, compared to about 80 percent of whites (122). Other polls have also indicated a significant difference in attitudes on these issues between blacks and whites (31).

Many caveats have been raised about the validity of survey findings in this complex area. The most important question is whether the findings reflect what individuals would choose for themselves if they were the patient described in the case situation. Neither of the surveys cited above asked what respondents would want for themselves.

One study in an outpatient medical center (113) asked respondents to suppose that they had such a severe memory loss that they could not identify people, remember where they were, or care for themselves, and that there was no chance of recovery. Sixty-two percent of the 152 respondents said they had thought a lot or a moderate amount about what treatment they would want in such a situation. Of these individuals, 73 percent said they would not want intensive care; 71 percent said they would not want CPR; 75 percent said they would not want tube feeding; and 53 percent said they would not want antibiotics for pneumonia. Patients over age 65 were more likely than those under age 65 to say they would not want tube feeding.

Anecdotal evidence suggests, however, that some patients who say that they would request withholding or withdrawal of life-sustaining treatments may not do so when actually faced with such a decision. OTA is not aware of any research that addresses this question.

The mass media and widely read professional journals contain commentaries criticizing physicians for their attitudes and handling of situations in which withholding or withdrawal of treatment may be appropriate. The criticisms are often based on anecdotes, and it is usually unclear whether the author believes that the problems occur regularly or rarely.

Physicians have been criticized in such commentaries for their reluctance or refusal to withhold or withdraw life-sustaining treatments and for their determination to postpone death until the last possible moment. It is said that physicians regard the death of a patient as a personal failure, that they sometimes do not consider the patient's experience of the treatment in decisions to initiate or continue it, and that they may be "seduced by technology" (47,65,80,81,164,219). Physicians and other health care professionals have also been criticized for pressuring families to consent to life-sustaining treatments for a severely debilitated or terminally ill relative against the better judgment of the family (135,164).

It has been suggested that a physician's need to treat may arise in part from a deep-seated fear of dying and that the same fear may cause some physicians and other health care professionals to withdraw from dying patients. It is said that this tendency to withdraw from a dying patient—experienced by the patient as abandonment—may be intensified when life-sustaining treatment has been withheld or withdrawn thus signifying that the patient's condition is considered hopeless (80, 100,186,219).

Physicians have also been criticized for practicing "defensive medicine"—i.e., providing all possible treatments regardless of their value to the patient in order to avoid a possible lawsuit.

Lack of physician training in how to care for dying patients whose diseases cannot be cured is said to leave some physicians feeling helpless when faced with such patients (80,89,100,219) (see also ch. 10). One physician reported this experience during a 1984 hospital strike:

> **One night, at 2:00 AM, while working as a nurse's aid, I was called to a patient under my care who had breast cancer with diffuse metastasis. She was on high doses of analgesics and nar-**

> cotics, but her pain was becoming refractory (not readily yielding to treatment). I was called to see her as a physician for chest pain attributed to rib metastases. There was not much I could do to relieve her discomfort except to start a morphine drip.
>
> Feeling helpless and frustrated, I called the nurse for assistance with this clinical problem. The nurse held the patient's hand, then plumped her pillow and straightened her bed, massaged the back of her hand and asked the names of her grandchildren. There I was, with the body of clinical medical knowledge to call upon, but inadequately trained in the effectiveness of compassion and empathy. Eventually the nurse soothed the patient, had her close her eyes, and she fell into golden slumber without the need for further narcotics (180).

In some instances, the feeling of helplessness caused by lack of an effective medical remedy for the patient's problem may lead physicians to initiate life-sustaining treatments that may not benefit the patient.

While recognizing the validity of some of these criticisms, physicians and others raise many counter arguments. First, they point out that it is frequently difficult to formulate an accurate diagnosis and prognosis and to determine how a particular patient will respond to a given treatment. In the face of this uncertainty, many physicians prefer to "err on the side of life" and initiate treatment (90,110,140,225).

Some physicians and others point out that there is almost always some chance a patient's condition will improve. In a recent, widely publicized case, for example, a 44-year-old woman who had been in a coma for 6 weeks and experienced cardiac arrest, a collapsed lung, and pneumonia, suddenly came out of the coma, 6 days after a Maryland judge denied her husband's petition to terminate life-sustaining treatment (4).

A physician reported a similar case:

> A-70-year-old man was admitted to a coronary care unit after he was found comatose at home. The doctor, knowing that the patient had had a massive heart attack 3 years earlier and seeing his current condition, advised the family that he would probably die, that if he lived, he would have severe brain damage, and that therefore aggressive treatment should probably not be used.
>
> While the doctor was talking to the family, however, the house staff ordered aggressive life-sustaining treatment. When the doctor learned of this, he was distressed but did not change the orders. The patient remained comatose that night. By the next morning, however, he had removed the mechanical ventilator himself and was talking, although his thinking was not clear. Four years later, the doctor reports, "the patient now visits my partner every couple of months for a check on his blood pressure and to monitor the propranolol he is taking to prevent sudden death" (35).

Even though such cases are rare, they intensify the doubts of physicians and others about withdrawing treatment.

Physicians point out that treatment of severely debilitated and terminally ill patients is a process—not a single event during which a life-or-death decision is made. Daily care of such patients involves many decisions, each affecting whether the patient will survive. Even when prognosis is very poor, physicians have difficulty knowing exactly when to stop aggressive care and begin palliative or supportive care.

Some physicians and others believe that physicians have a duty to prolong life; that it is unethical for them to withhold or withdraw life-sustaining treatment; and that such behavior destroys the trust that underlies the physician-patient relationship. Others believe that continuing treatments that do not benefit the patient or treatments that are against the wishes of the patient destroys this trust.

A survey of the attitudes of 250 physicians, nurses, and social workers at three VA medical centers suggest that some life-sustaining treatments are more difficult to withhold or withdraw than others. The study found that these health care professionals were most comfortable with Do-Not-Resuscitate (DNR) orders and withholding surgery and most uncomfortable with decisions to withhold nutritional support and hydration. In the middle range were decisions to withhold antibiotics. Withholding treatment was perceived as less difficult than withdrawing it (230).

Some physicians and other health care professionals are reluctant to withhold or withdraw life-sustaining treatment because they have experienced instances in which terminally ill or severely debilitated patients who seem to be suffering greatly and perhaps wanting to die, in fact want continued treatment (69,78,90). One newspaper reported the following incident:

> **A 77-year-old woman dying of lung disease in the intensive care unit of a New York City Hospital had been on a mechanical ventilator for six months. No treatment was known that could improve her condition, and it was expected that she would be dependent on the ventilator until she died. Physicians in the ICU regarded her life as very difficult and believed that she might prefer to have the ventilator removed and die.**
>
> **The doctor raised the issue with her. "Now, I don't want this to upset you. Nothing has changed in your situation. But we have to ask you this now so we will be better able to handle your care."**
>
> **She was not able to speak because of the ventilator, but she smiled.**
>
> **"We are not optimistic we can take you off the ventilator," he continued. "We've known that for a while, and we're looking to send you to a nursing home. But we need to know, if something unexpected should happen, if you should have an irregular heartbeat, do you want us to resuscitate you?"**
>
> **The frail woman paused for a moment. And then she nodded.**
>
> **"You understand what I am asking?"**
>
> **She nodded again.**
>
> **"As it stands, you want everything done?"**
>
> **To the surprise of the doctor and two others standing at her bedside, she nodded yes again (97).**

Some physicians and other health care professionals may also be reluctant to withhold or withdraw life-sustaining treatment because they have experienced instances in which patients decided against treatment because they were depressed, in pain, or in significant discomfort, but when these problems were relieved, the patients decided in favor of treatment. Others may have experienced instances in which patients refused life-sustaining treatment because they feared the procedures or equipment but changed their minds when the procedures were explained (90). Instances in which patients change their minds for these or any other reason tend to reinforce the general preference of health care professionals to "err on the side of life."

Opinions About "Quality of Life" as a Factor in Decisions About Life-Sustaining Treatment

Opinions about whether "quality of life" should be a factor in decisions about life-sustaining treatment vary depending on what is meant by the term, but its meaning is seldom made explicit. The term may refer to:

- an individual's view about the quality of his or her own life,
- an observer's assumption about how the individual views the quality of his or her own life, or
- an observer's evaluation of the quality of the individual's life.

From any of these three points of view, a judgment about an individual's "quality of life" may be based on physical, mental, emotional, or social characteristics of the individual or his or her environment. Severe cognitive impairment and patient physical or emotional suffering are frequently mentioned as aspects of poor "quality of life."

Whether "quality of life" should be considered in decisions about life-sustaining treatments is probably the point of greatest disagreement between advocates of "death with dignity" and advocates of "the right to life." In the opinion of advocates of "death with dignity," "quality of life" *from the patient's point of view* should be a primary consideration in decisions about life-sustaining treatment.

Advocates of "the right to life" argue, in contrast, that opinions about "quality of life" are, or tend to become, judgments about the value of life, and that treatment decisions based on "quality of life" devalue it. According to one spokesperson for this position:

> "Quality of life" talk abandons the substantive concept of "life" in its focus on "quality," suggesting the extreme position that a life of poor health quality is probably not even a properly human life at all; not worth living, and not worth keeping alive (149).

This position is usually based on an underlying conviction about the sanctity of life. For example, in testifying before the Senate Subcommittee on Family and Human Resources, Paul Ramsey said:

> Our nation is in a deep moral crisis, a crisis of which road to take, the high road of faithfulness to a fundamental principle of Western morality—*the equality of life*—or the low road of discretionary judgments concerning the *quality of a life*, permitting private persons to assess that life's inherent *capability* or *worthiness* to be treated equally, protected equally, as any other life would be treated and protected.
>
> In our moral heritage, *equality of life* stems from the traditions of the religions of Western culture, whose teaching is that each of us has his *title* to life from God, from not only nature but nature's God, and certainly not from any State's or societal or private judgment that that life may or may not be entitled to equal care and protection. In my view, the equality of life can be sustained as a fundamental principle by acceptable notions of the equal dignity, equal claims, of any life in a valid, *truly humanistic* morality (159).

Advocates of "the right to life" believe that allowing "quality of life" considerations in decisions about life-sustaining treatment for any persons in the society creates a dangerous precedent that could ultimately threaten the fundamental rights of handicapped people of all ages and subject them to abandonment, abuse, and medical neglect (24, 79,149).

Little is known about the attitudes of physicians and other health care professionals toward the use of "quality of life" as a factor in health care decisions. One study asked physicians to indicate how they would treat a hypothetical patient—a 69-year-old nursing home resident in severe respiratory failure—and what factors in the case influenced their decision. Results of the study show that 37 percent of the physicians based their decision at least in part on the patient's "quality of life," including 49 percent of physicians who said they would withhold mechanical ventilation but only 29 percent of those who said they would provide the treatment. The researchers note, however, that the physicians varied greatly in their opinions about the "quality of life" of the hypothetical patient (147).

Because of the lack of a clear and accepted definition of "quality of life" and because of the value judgments it introduces into the decisionmaking process, some people believe that "quality of life" should not be a factor in decisions about life-sustaining treatment and that such decisions should be based only on factors such as expected medical outcome. Others believe that "quality of life" is an important component of outcome and thus a necessary factor in treatment decisions.

The difficulty of determining whether "quality of life" should be a factor in decisions about life-sustaining treatment is summed up in the following comment of one observer:

> I am struck by how many in my limited circle of acquaintances are willing to use and apply measures of the quality of life, and how few of them are comfortable with a serious and sustained probing of precisely what it is. Many of us are apt to respond as Fats Waller did when asked to explain the nature of jazz. "Man," he said, "if you don't *know* what it is, don't mess with it." In the context of geriatric care, we cannot leave it there—though perhaps it will turn out that we ought not to mess with it (175).

Chapters 5 through 9 discuss what is known about the use of factors that are sometimes said to constitute "quality of life" in decisions about the five technologies OTA studied.

Attitudes About the Patient's Role in Decisions About Life-Sustaining Treatment

Intertwined with opinions about life-sustaining technologies, withholding and withdrawal, and "quality of life"—but not synonymous with such opinions—are attitudes about the patient's role in decisions about life-sustaining treatment. These attitudes exist within the context of general societal attitudes about the importance of patient autonomy and patient involvement in decisions about all kinds of medical care. These general societal attitudes may be based on:

1. growing awareness that decisions made without the patient's input may not reflect his or her wishes or best interests;
2. widespread skepticism about what is seen as the traditional paternalistic role of physicians;
3. court rulings that support patient autonomy in decisions about medical treatment (see ch. 3); and
4. societal concerns about individual rights, civil rights, and consumer rights that, although not directly related to medical decisionmaking, still affect attitudes about it (91,228).

In this general context, physicians have been criticized for failing to discuss treatment decisions of all kinds with their patients. The extent of this problem is unclear. A 1982 survey, conducted for the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, found that the vast majority of physicians (84 to 98 percent) said they usually discuss diagnosis, prognosis, and the pros and cons of treatment with their patients. A smaller, but still significant proportion of adults interviewed for the same survey (68 to 78 percent) agreed that their physicians usually discuss these matters with them (118). No data are available to determine whether physicians discuss decisions about life-sustaining treatments with patients more or less often than decisions about other treatments.

Many hypotheses have been advanced as to why some physicians do not discuss treatment decisions with some of their patients. Survey data show that physicians believe that about 20 percent of their patients are incapable of understanding treatment options and that other patients who are capable of understanding are, nevertheless, incapable of coping with information about their condition and treatment for it (118).

One observer points out that in the past physicians had few specific remedies for diseases and relied on hope and reassurance to comfort their patients. These approaches depend on patient trust, and physicians learned not to undermine trust by disclosing their uncertainty about diagnosis, prognosis, or appropriate treatment. According to this view, some physicians may fail to discuss treatment decisions with patients because of reluctance to acknowledge uncertainty (95).

Although most people believe physicians are sometimes justified in withholding information from patients or overriding a patient's decision about treatment, in general, people strongly support the autonomy of the patient in the decisionmaking process (118). A 1985 poll of 1,500 Americans age 45 and over found that only 14 percent agreed with the statement, "A person who has a fatal illness with no possibility of recovery should receive all available types of life support to keep them alive *regardless of their own wishes*" (emphasis added). Eighty-one percent disagreed, and 4 percent did not know. No significant differences were found by age (5-year intervals to age 85) (155).

In response to a second statement, "People who have made their wishes known about life support treatments should have their wishes followed, regardless of the opinions of physicians or family members," 81 percent of respondents agreed, 13 percent disagreed, and 6 percent did not know (155).[2]

As discussed earlier, questions have been raised about the validity of survey findings in this area. Critics point out that the findings may reflect the respondents' attitudes about patient autonomy in general and not necessarily the way respondents want decisions made for themselves.

In fact, many health care professionals doubt that the majority of patients actually want to make decisions about medical treatments themselves. One study of patient participation in decisions about treatment for hypertension supports this view. Although most of the subjects wanted information about their condition and its treatment, 78 percent preferred that a physician or nurse practitioner make the decision about treatment, and less than half of these even wanted the physician or nurse practitioner to consider their opinions. Only 19 percent wanted to participate equally in decisionmaking, and only 3 percent wanted to make the decision themselves. Higher income and education were correlated with an individual's desire to participate equally in decisionmaking (178).

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[2] OTA appreciates the generosity of the American Association of Retired Persons (AARP) in including these questions in its 1985 poll and providing the results for use in this report.

Results of another survey showed that fewer elderly than younger people wanted to make decisions about their own treatment in the event that they are "seriously ill" (see table 2-1). While 43 percent of respondents of all ages said they wanted to make the final choice, only 23 percent of those over 65 wanted to do so (118).

Table 2-1.—Responsibility for Decisions About Medical Treatment, Louis Harris Poll, 1982

Question: If you were seriously ill, would you want the responsibility of making the final choices about your medical treatment or would you want your doctor to make them for you?

	Age				
Response:	All ages %	18-34 years %	35-50 years %	51-64 years %	65 and over %
Patient makes final choices	43	56	45	29	23
Doctor makes final choices	38	28	36	47	60
Both	14	14	15	17	12
Not sure	4	3	3	6	2

SOURCE: Louis Harris & Associates, "Views of Informed Consent and Decisionmaking: Parallel Surveys of Physicians and the Public," President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Health Care Decisions*, vol. II (Washington, DC: U.S. Government Printing Office, 1982).

Views on Surrogate Decisionmaking

Survey data indicate that most people want a family member to make treatment decisions for them if they are decisionally incapable (see table 2-2). Yet a significant percentage would rather have their physician or a friend or lawyer make decisions for them in such situations (118).

Table 2-2.—Who Should Make Treatment Decisions When the Patient is Too Sick To Decide, Louis Harris Poll, 1982

Question: If you were too sick to make an important decision about your medical care, who would you want to make the final decision for you—a family member, a close friend, your doctor, or a lawyer appointed to protect your interests?

Response	Percent
A family member	57
A close friend	2
Your doctor	31
A lawyer	2
Doctor and family/friend	6
Other	a
Not sure	1

[a] Less than 0.5 percent.

SOURCE: Louis Harris & Associates, "Views of Informed Consent and Decisionmaking: Parallel Surveys of Physicians and the Public," President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Health Care Decisions*, vol. II (Washington, DC: U.S. Government Printing Office, 1982).

Some physicians believe that asking families for a decision about life-sustaining treatment is too stressful for the family and that families should not be asked to make these decisions. Others point out that the decisions of family members do not always reflect the patient's wishes or best interests. In some cases, family members insist on aggressive treatment that is considered inappropriate by the physician and other health care professionals. In other cases, family members decide that treatment should be withheld or withdrawn for reasons that may be related to the needs of the family rather than the wishes or best interests of the patient. As a result, many physicians and others believe that families should not have an absolute right to make these decisions (33,76, 90,110,116,172,177). According to two proponents of this viewpoint:

> We submit that the family's rights vis-à-vis the medical care of an adult are limited to ensuring that the wishes of the patient are fulfilled and to expressing their considered judgment regarding what is in the best interest of the patient, given their presumably more intimate knowledge of the patient and his life and values. None of this, however, entails the proposition that a physician ought to acquiesce to any and every desire expressed by a family concerning the appropriate medical care for an incompetent patient.
>
> However sensitive the physician must be to the emotions and concerns of family members, he ought to remember that his covenant is with the patient, not the family. It is a covenant to pursue the welfare of the patient, not the welfare of society or even the welfare of the family. When the patient cannot speak for himself, we believe that the physician must, to the best of his or her abilities, speak for the patient (172).

The foregoing discussion raises many questions about how decisions about life-sustaining treatments are actually made, the usual roles of physicians, other health care professionals, and families, and the extent to which patients are or could be involved in the decisionmaking process. Because of the complexity of the clinical, legal, and ethical issues surrounding surrogate decisionmaking, OTA commissioned three papers on this topic and sponsored a workshop on "Making Medical Decisions for Mentally Impaired Adults." Some conclusions of the workshop and the commissioned papers are incorporated in this report. For a more detailed and comprehensive presentation of the issues, the reader is referred to the papers that will be published by *Milbank Memorial Fund Quarterly* (50) or can be obtained from the National Technical Information Service (see app. A).

Opinions About Euthanasia

Euthanasia, or mercy killing, is an act intended to cause the death of a person who is suffering from what is believed to be an incurable condition. The manner of death is intended to be painless or at least to result in less suffering for the individual than continuation of his or her existence as it is.

Many people make a distinction between an act such as giving a patient a drug that causes death, which they call euthanasia, and withholding or withdrawing life-sustaining treatments, which they do not call euthanasia. Other people refer to an act such as giving a patient a drug to cause death as "active euthanasia" and distinguish it from withholding or withdrawing life-sustaining treatment, which they call "passive euthanasia"; many of these people believe that there are significant legal and ethical differences between active and passive euthanasia. A third group of people believes that the distinction between active and passive euthanasia is not meaningful and that both practices are morally wrong.

With regard to what is sometimes called "active euthanasia," the National Opinion Research Center has asked the following question periodically since 1947:

> When a person has a disease that cannot be cured, do you think doctors should be allowed by law to end the patient's life by some painless means if the patient and his family request it?

In 1947, 37 percent of respondents said yes. By 1973, slightly over half said yes, and in 1983, 63 percent said yes (122). Similarly, 61 percent of respondents to a 1985 Harris poll agreed that a "patient who is terminally ill, with no cure in sight, ought to have the right to tell his doctor to put him out of his misery" (181).

In contrast to these attitudes, most religions and most ethical traditions oppose euthanasia (103) (see ch. 4). The American Medical Association prohibits any involvement of physicians in euthanasia (9), and survey results indicate that far fewer physicians than other adults consider euthanasia acceptable. For example, one survey asked:

> Imagine that a dying patient in severe distress, which cannot be relieved, asks to have his life ended. Under these circumstances, is it ethically permissible to comply with the patient's wishes?

Only 4 percent of physicians said yes, and only 2 percent said they would be likely to comply with such a request (118). On the other hand, more than 80 percent of physicians agreed that it is ethically permissible to administer pain relieving drugs to a dying patient in severe distress, even if the required dose would shorten the patient's life.

Euthanasia, or mercy killing, is most likely to occur when patients are believed to be incurably ill and suffering but unlikely to die imminently. Recent newspaper articles have reported the following:

- A 68-year-old woman in Lynchburg, VA, stabbed her 72-year-old husband to death with an icepick because he was "confused and screaming with pain" caused by cancer (21).
- An elderly Florida man shot his wife to death in the nursing home where she lived because she had Alzheimer's disease and spent much of her time screaming (122).
- An 86-year-old man shot his wife to death in her hospital bed because she had Alzheimer's disease. He then shot and killed himself (123).
- A woman in La Jolla, CA, strangled her 92-year-old husband in his sleep because he was bedridden, suffering from emphysema, arteriosclerosis, strokes, and hallucinations (122).

In general, mercy killing is considered only when a patient is not receiving a life-sustaining treatment that could be withheld or withdrawn. Allan Otten, a correspondent for the Wall Street

Journal, describes such a situation in an article entitled "Can't We Put My Mother to Sleep?"

> **Every few days now, I go to visit my 90 year old mother in a nearby nursing home, more to salve my own conscience probably than to do her any meaningful service. For her, in fact, there is little I can do. She lies on her side in bed, legs drawn rigidly into the fetal position, blinks at me uncomprehensively as I prattle on about family doings, and rarely utters a sound except a shriek of pain when the attendants turn her from one side to the other in their constant battle to heal her horrible bedsores. She must be hand-fed, and her incontinency requires a urethral catheter.**
>
> **Why do we treat our aged and loved animals better than we treat our aged and loved human beings? Shouldn't a humane, caring society—as ours is supposed to be—begin to consider ways to put my long-suffering mother, and the steadily growing number of miserable others like her, peacefully to sleep (146)?**

Otten says that he was told by several doctors and ethicists to take his mother home, bathe her, keep her comfortable, and just let her die. He asks in response whether "it must be done this slow, hard way" and whether "a pill, injection, or other humane method" could be found to end her suffering (146).

Reports like this one speak to the intense anguish that some people feel about what they perceive as the prolonged suffering of a relative or friend. Responses to Mr. Otten's article ranged from sympathy and support to outrage that he would want "to kill his 90-year-old mother" (72, 224).

Mercy killing is illegal, but most people have not been prosecuted for it, or if prosecuted, they have been acquitted or given probation. There are exceptions, however, and a few individuals have been prosecuted and convicted (17).

Euthanasia seems to be more widely accepted and perhaps more widely practiced in some other countries than in the United States. In 1984, a group of French doctors announced that they had helped some patients to die by active measures, including the use of medications. Their declaration stated:

> The moment has come for medical training and institutions to respond to the demand for quality in the last period of life and a death that prevents suffering and preserves dignity (29).

Simultaneously, results of a poll were published showing that 80 percent of French doctors favor euthanasia for hopelessly ill patients (29).

In the Netherlands, the Dutch Association for Voluntary Euthanasia has a group of volunteers to answer questions and give advice about euthanasia and a group of doctors who are in principle willing to perform euthanasia. The association insists that the patient must wish to die himself or must be unconscious. It has published a booklet detailing the drugs that can be used for mercy killing (2). Euthanasia is illegal in the Netherlands, but few doctors who perform euthanasia are prosecuted. In 1985, the Dutch Government Commission on Euthanasia recommended national legislation that would exempt physicians from prosecution for euthanasia if mandated procedures are followed. This legislation has not been enacted (42).

The diversity of opinions and attitudes just described with regard to life-sustaining technologies, withholding and withdrawing treatment, "quality of life" as a factor in treatment decisions, patient autonomy, surrogate decisionmaking, and euthanasia suggest that individuals involved in a decision about life-sustaining treatment are likely to differ in their perceptions of the situation and their beliefs about how the decision should be made and what the decision should be. Such differences of opinion can occur in decisionmaking situations that involve only a physician and a patient or a single family member. They are more likely to occur, however, when more people are involved, as they often are in hospitals, nursing homes, and other multiperson treatment settings.

Many people feel very strongly about one or more of the issues discussed in this section. This intensity of feeling may be based on strong religious or moral convictions, prior experience, professional training and socialization, or deeply ingrained cultural values and mores. The seriousness and potential finality of decisions about life-sustaining treatment and the emotionally charged atmosphere that usually surrounds severe illness and the possibility of an individual's death further intensify these strong feelings and beliefs. Even individuals who do not feel strongly about these issues in the abstract frequently develop strong opinions in decisionmaking situations that involve them personally. Thus, decisions about life-sustaining treatments are likely to take place in the context of intense and divergent feelings, beliefs, and attitudes of participants and potential participants.

SOCIETAL RESPONSES TO THE DILEMMAS ASSOCIATED WITH LIFE-SUSTAINING TECHNOLOGIES

Although life-sustaining technologies have had a positive effect in general, the dilemmas associated with their use in some cases have given rise to legal and ethical debate; court rulings; new methods for the determination of death; State legislation for living wills and methods for designating a surrogate decisionmaker; guidelines for decisionmaking formulated by government-appointed task forces and commissions, citizens' groups, professional associations, and others; institutional policies for decisionmaking and institutional ethics committees; Federal regulations; and hospice programs. This section reviews each of these developments briefly as background for subsequent chapters.

Legal and Ethical Debate

Some issues raised in this report have been discussed since ancient times, but legal and ethical debate about issues related to the use of life-sustaining treatments has intensified since the 1950s as a result of the introduction of new medical technologies. Since then a large body of knowledge has been developed, consisting in part of legal concepts and legal analysis and in part of ethical principles and ethical analysis (see chs. 3 and 4). Legal and ethical aspects of the debate about life-sustaining treatments are interrelated. Moreover, legal and ethical analysis has stimulated many of the other developments discussed in this section and in turn has been stimulated by them.

Observers have noted that each new technology seems to raise new and to some extent unexpected legal and ethical issues (32,33). Yet most of the debate about these issues has not focused on specific technologies. In addition, although there are exceptions, most legal and ethical analysis of these issues has not focused on elderly people as a distinct group.

Finally, until recently, legal and ethical debate has focused more on decisions about withholding and withdrawal—i.e., when it is legal or ethical to withhold or withdraw life-sustaining treatment—than on questions of access or right to treatment—i.e., what treatment is society legally or ethically obligated to make available. As concern has grown about the impact of cost containment measures on access to care, however, legal and ethical debate has focused increasingly on questions of access and right to treatment.

Court Cases

The first court case to focus national attention on the issue of withdrawing life-sustaining treatment was that of Karen Quinlan, a 21-year-old woman who was comatose and receiving mechanical ventilation. In 1976, the New Jersey Supreme Court ruled that her father could request removal of the ventilator on her behalf (88). (When it was removed, she began to breathe on her own and lived another 10 years.)

Since the landmark *Quinlan* ruling, many other cases involving life-sustaining treatments have been decided. Table 2-3 lists the cases OTA is aware of that involve elderly people. Many of these cases are discussed in other chapters of the report. Legal cases are not usually categorized by the age of the individual involved, and this table is not intended to suggest that different legal principles apply or should apply to elderly people. It is rather intended to show which technologies are represented in cases involving elderly people and the apparent change in this aspect of such cases over the past 10 years.

It is clear from table 2-3 that from 1980 to 1985 most cases involved the use of mechanical ventilation. The first rulings on cases involving nutritional support for elderly patients were handed down in 1984. One case involving nutritional support was decided in 1985; there were eight cases in 1986, and two as of early 1987. These figures indicate that the legal issues associated with the

Table 2-3.—Legal Cases Involving Decisions About Withholding or Withdrawal of Life-Sustaining Treatment From Elderly Patients

State	Patient's age	Case	Technology
1977:			
Massachusetts	67	*Superintendent of Belchertown State School v. Saikewicz*	Chemotherapy
1978:			
Massachusetts	67	*In re Dinnerstein*	Resuscitation
Massachusetts	77	*Lane v. Candura*	Amputation of gangrenous leg
New Jersey	72	*In re Quackenbush*	Amputation of gangrenous legs
Tennessee	72	*State Department of Human Service v. Northern*	Amputation of gangrenous feet
1980:			
Massachusetts	78	*In re Spring*	Dialysis
Ohio	70	*Leach v. Akron General Medical Center*[a]	Mechanical ventilation
Florida	73	*Satz v. Perlmutter*	Mechanical ventilation
1981:			
New York	83	*In re Eichner*	Mechanical ventilation
California	67	*Foster v. Tourtellotte*	Mechanical ventilation
1983:			
New Mexico	65+[b]	*New Mexico ex rel. Smith v. Fort*	Dialysis
Washington	69	*In re Colyer*	Mechanical ventilation
Texas	65+[b]	*In re Guardianship Estate of Peterson*	Mechanical ventilation
1984:			
New York	88	*In re Moschella*	Mechanical ventilation
California	70	*Bartling v. Superior Court*	Mechanical ventilation
Florida	65+[b]	*John F. Kennedy Memorial Hospital Inc. v. Bludworth*	Mechanical ventilation
Ohio	70	*Leach v. Shapiro*[a]	Treatment against patient wishes/ mechanical ventilation
Arizona	82	*Lurie v. Samaritan Health Service*	Mechanical ventilation
Massachusetts	92	*In re Hier*	Nutritional support
New York	85	*In the Matter of Application of Plaza Health and Rehabilitation Center*	Nutritional support
1985:			
Washington, DC	71	*Tune v. Walter Reed Army Medical Center*	Mechanical ventilation
New Jersey	83	*In re Conroy*	Nutritional support
New York	70	*Saunders v. State*	Living will[c]
1986:			
New York	83	*In re Triarsi*	Mechanical ventilation
New York	79	*In re Vogel*	Nutritional support
New York	83	*In re Application of Kerr (O'Brien)*	Nutritional support
New Jersey	90	*In re Visbeck*	Nutritional support
Hawaii	73	*Wilcox v. Hawaii*	Nutritional support
Florida	73	*Corbett v. D'Alessandro*	Nutritional support
Virginia	65+[b]	*Hazelton v. Powhatan Nursing Home, Inc.*	Nutritional support
Arizona	70	*Rasmussen v. Fleming*	Nutritional support/resuscitation
Ohio	79	*Galvin v. University Hospitals*	Treatment against patient wishes/ resuscitation
California	75	*Cantor v. Weiss*	Nutritional support
1987:			
New York	79	*Workman's Circle Home and Infirmary for the Aged v. Fink*	Nutritional support
California	92	*Gary v. California*	Nutritional support
New Jersey	91	*McVey v. Englewood Hospital Association*	Treatment against patient wishes/ mechanical ventilation

[a] The 1980 case *Leach v. Akron General Medical Center* concerned a petition by Mrs. Leach's husband for an order to discontinue mechanical ventilation for her. The 1984 case *Leach v. Shapiro* involved an action for damages against the doctor and hospital for the time Mrs. Leach was on mechanical ventilation. Both cases are discussed in ch. 3.

[b] The precise age of the patients in these cases is not known, although they are known to be over 65.

[c] The patient sought prior judicial validation of her living will so that it could be carried out without delay if her condition deteriorated to the point at which she would want to refuse life-sustaining treatment.

SOURCE: Office of Technology Assessment, 1987.

use of nutritional support are now most controversial.

Most recent court decisions in cases of younger patients also involve the use of nutritional support. Some cases of younger people are discussed in other chapters.

Determination of Death

Standards for the determination of death are relevant to decisions about life-sustaining treatment because everyone agrees that such treatment should not be used for persons who are already dead. Two decades ago, the accepted standard for determining death was the permanent absence of respiration and circulation. Since then, determination of death has become more complex because respiration and circulation can be maintained by artificial means even when the brain centers that control respiration no longer function and the whole brain, including the brain stem, is dead (106,151). The concept of brain death evolved as a solution to this problem.

In 1968, an Ad Hoc Committee of the Harvard Medical School issued an influential report defining what the Committee called "irreversible coma" and listing four clinical criteria for determining it: 1) unreceptivity and unresponsitivity to even the most painful external stimuli; 2) no spontaneous movements or breathing; 3) no reflexes; and 4) a flat electroencephalogram. It was stressed that these four conditions should remain unchanged for at least 24 hours and exist in the absence of hypothermia and central nervous system depressants (1). These criteria have been widely used to determine brain death. One problem has been the Harvard Committee's use of the term "irreversible coma," which suggests to some people that the criteria indicate permanent unconsciousness rather than brain death (92,151).

Beginning in 1970, many States enacted legislation recognizing brain death, but lack of uniformity in the wording of these statutes, and thus lack of agreement about when death had occurred led to many proposals for a uniform legal definition of death. When the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was created in 1978, the problem of defining death was included in its mandated studies. In 1981, the Commission recommended a model State statute, the Uniform Determination of Death Act, that defined death as follows:

> An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead (151).

The Commission concluded that the "determination of death must be made in accordance with accepted medical standards" (151) but that the standards should not be included in State statutes or regulations because the tests for determining death may change with the advent of new research and technologies. The Commission's report, *Defining Death*, includes as an appendix clinical guidelines for determining death formulated by the Commission's medical consultants.

Despite the recommendations of the President's Commission, controversy and confusion about some aspects of the determination of death persist. Moreover, some religious groups, such as Orthodox Jews, oppose the concept of brain death because it violates their belief that a person is alive until his or her heart and lungs have stopped functioning.

State Legislation Authorizing Living Wills and Methods for Designating a Surrogate Decisionmaker

In response to the dilemmas associated with decisions about life-sustaining treatment for persons who are not decisionally capable, some States have passed legislation authorizing living wills—documents that give directions from an individual about that person's preferences about life-sustaining treatments in the event that he or she becomes decisionally incapable in the future. The first living will legislation was enacted by California in 1976, and seven States followed suit in 1977. During the next 6 years, only six States and the District of Columbia enacted living will legislation. In 1984, the pace picked up, partly because of growing public support for the terminally ill person's right to refuse unwanted treatment and partly because of an apparent softening in the Catholic Church's opposition to such legislation.

Between 1984 and 1986, 24 States passed living will statutes. Thus, 38 States and the District of Columbia now have such statutes.

Living will statutes in some States allow individuals to appoint a surrogate—a relative, friend, lawyer, physician, or other person—to make health care decisions for them if they become decisionally incapable. In addition, all 50 States and the District of Columbia, have durable power of attorney statutes that allow individuals to appoint a surrogate decisionmaker. General durable power of attorney statutes were enacted primarily to authorize proxies for financial and property decisions, however, and there is some uncertainty about whether they also authorize health care decisions. In response to this uncertainty, 15 States have enacted legislation that specifically authorizes durable powers of attorney for health care (43).

Since 1976, 15 States have enacted family consent laws that give family members legal authority to make health care decisions for terminally ill or incapacitated adults (137). In States without family consent statutes or specific court decisions, there is still no legal authority for the widespread practice of allowing family members to speak for individuals who are not decisionally capable.

State guardianship laws allow a court to appoint someone to make decisions for persons who are adjudicated incompetent. Many guardianship laws, like general durable power of attorney statutes, predate concerns about the use of life-sustaining treatment for persons who are not decisionally capable and may not address these concerns adequately.

Living wills, durable powers of attorney, family consent laws, and guardianship laws are discussed in chapter 3.

Guidelines for Decisionmaking

In 1983, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research published its report *Deciding To Forego Life-Sustaining Treatment*. Based on the results of public meetings and the commission's earlier work on informed consent (152), defining death (151), and access to health care (154), the report discusses: the elements of good decisionmaking, factors that constrain the patient's decision, and special problems of patients who are decisionally incapable or permanently comatose (153). Some conclusions of the report are as follows:

- The voluntary choice of competent patients should determine whether or not life-sustaining treatments are given.
- Health care institutions and professionals should try to enhance patients' abilities to make decisions on their own behalf.
- Health care professionals should generally maintain a presumption in favor of life-sustaining treatment, while recognizing that competent patients may refuse treatment.
- Health care professionals may decline to provide a given treatment option if it would violate their conscience or professional judgment, but in doing so, they may not abandon the patient.
- Health care institutions or society may justifiably restrict the availability of certain treatment options in order to enhance equitable allocation of limited resources.
- An appropriate surrogate, ordinarily a family member, should be named to make decisions for patients who are not decisionally capable.
- Primary responsibility for ensuring that morally justified processes of decisionmaking are followed lies with physicians. However, health care institutions should develop policies to enhance patients' competence and provide for the designation of surrogates.
- Special attention should be paid to providing respectful, responsive, competent care for people who choose to forgo life-sustaining treatment.

The 1983 report of the President's Commission supports the establishment of institutional ethics committees and passage of State legislation authorizing living wills and durable powers of attorney for health care (153). It has had a strong impact on thinking about these issues over the past 4 years. Some "right to life" advocates object to the report, however, because they believe it is biased toward the "death with dignity" position.

Several State task forces and commissions have also studied or are studying issues associated with the use of life-sustaining treatment. For example:

- In Minnesota, in 1984, the State Coalition on Health Care Costs published its report, *The Price of Life: Ethics and Economics* (136), that discusses individual treatment decisions, allocation of health care resources, and rationing.
- In New York, a State Task Force on Life and the Law is studying the problem of discontinuing life-sustaining therapies for terminally ill people and other issues raised by new medical technologies.
- In New Jersey, a State Commission on Legal and Ethical Problems in the Delivery of Health Care is studying issues related to decisions about life-sustaining technologies and allocation of health care resources.

In other States, citizens' groups and groups associated with quasi-governmental Health Systems Agencies are also studying these issues. From 1982 to 1984, the Oregon Health Decisions Project, a privately funded project linked to the State citizens' advisory council on health policy, held meetings in local communities and with professional groups to develop guidelines for health care decisions and proposals to improve medical decisionmaking in the State. The project resulted in a 1984 meeting at which delegates approved a document entitled *Society Must Decide*, that delineates principles and specific policy recommendations for patient autonomy, access to services, cost control, and resource allocation (46). Similar projects are underway in Idaho, New Jersey, Wisconsin, Washington, and Orange County, California. In Colorado, the State Hospital Association has developed an educational game called "Critical Choices" to simulate difficult ethical dilemmas in health care decisionmaking (218).

Professional societies have also issued guidelines for decisionmaking. In 1982, the Judicial Council of the American Medical Association issued a statement on quality of life and care of the terminally ill. It said in part:

> In the making of decisions for the treatment of . . . persons who are severely deteriorated victims of injury, illness, or advanced age, the primary consideration should be what is best for the individual patient and not the avoidance of a burden to the family or to society. Quality of life is a factor to be considered in determining what is best for the individual.
>
> The social commitment of the physician is to prolong life and relieve suffering . . . For humane reasons, with informed consent a physician may do what is medically necessary to alleviate severe pain, or cease or omit treatment to let a terminally ill patient die, but he should not intentionally cause death . . . Where a terminally ill patient's coma is beyond doubt irreversible and there are adequate safeguards to confirm the accuracy of the diagnosis, all means of life support may be discontinued (9).

In 1986, the AMA Council on Ethical and Judicial Affairs amended this statement to add that nutrition, hydration, and medications are among the "life-prolonging" treatments that may be withheld or withdrawn from persons who are terminally ill and persons who are irreversibly comatose even if death is not imminent (10).

In 1985, the Minnesota Medical Association issued a statement, "Health Care for the Elderly—A Minnesota Physician's Perspective," that discusses the roles and responsibilities of patients and physicians in decisions about life-sustaining treatments (105). Many other State and local medical associations have also issued guidelines for decisions about these treatments (12,13,15,117).

In 1984, the American Geriatrics Society issued a statement endorsing the patient's role in decisionmaking and the use of advance directives. It stated that "the patient's interests are not always best served by applying all theoretically beneficial treatments" and that patients should be offered a full range of treatment options, "including the option of supportive care for patients who are dying" (5).

Organizations that represent hospitals, nursing homes, and other health care facilities have also issued statements about patients' and physicians' rights and responsibilities in making medical decisions, but these organizations have generally stopped short of defining specific procedures that should be followed in making such decisions. The American Hospital Association's "Patient's Bill of Rights" (8), issued in 1973, endorses the patient's right to receive information about his or her diagnosis, treatment, and prognosis, and "to refuse treatment to the extent permitted by law." The American Hospital Association has encouraged the development of institutional policies for decisionmaking (3,160).

In 1982, the American Health Care Association, an association that represents nursing homes, issued a report on methods for designating a surrogate and making medical decisions for questionably competent nursing home residents (6). In 1984, the Association circulated a report on "Health Care Decisionmaking in Long-Term Care Facilities," which encourages the development of institutional policies for "life-and-death" decisions and discusses the considerations that should be included in such policies (7).

This OTA report does not analyze the views of different religious groups about life-sustaining treatments. It is important to note, however, that many different groups have issued statements on the subject that have profound impact on the attitudes and beliefs of their members. The statements of the Catholic Church have had a particularly strong impact. They include Pope Pius XII's 1957 statement on ordinary v. extraordinary treatments (150) and the "Declarations on Euthanasia" issued by the Sacred Congregation for the Doctrine of the Faith in 1980 (166) (see ch. 4).

In 1983, the Law Reform Commission of Canada released a report, *Euthanasia, Aiding Suicide, and Cessation of Treatment*, that recommends that euthanasia (the intentional killing of a person for compassionate motives) and aiding suicide remain illegal in Canada. The report also states that competent patients have a right to refuse any medical treatment and that treating patients against their will is assault under criminal and civil law in Canada (104). It states that a presumption in favor of treatment should be maintained but that "quality of life" can be considered in treatment decisions, and that a patient's incompetence does not require that physicians provide aggressive treatment in all circumstances. Finally, the report concludes that physicians, rather than courts, ethics committees, or families, should be legally responsible for ensuring that the patient's rights and best interests are upheld in the decisionmaking process (48,104,177).

Institutional Policies

In response to a perceived need in individual facilities and to the recommendations of national and State commissions and professional associations, some hospitals and nursing homes have developed institutional policies for decisions about life-sustaining treatment. Institutional policies can specify that certain treatments are routinely used or not used for certain kinds of patients; they can designate a procedure for making treatment decisions; or both. Most existing institutional policies for decisionmaking address only decisions about resuscitation. A 1986 survey by the Joint Commission on Accreditation of Hospitals (JCAH) found that 57 percent of hospitals, 20 percent of nursing homes, and 43 percent of hospices had formal policies for decisions about resuscitation (115) (see ch. 5 for a discussion of institutional policies for decisions about resuscitation). Only 20 percent of hospitals, 15 percent of nursing homes, and 21 percent of hospices had formal institutional policies for decisions about other life-sustaining treatments.

A 1983 survey of hospitals in Minnesota found that 86 percent had policies allowing physicians to write Do-Not-Resuscitate (DNR) orders, and 44 percent had written protocols defining how DNR decisions should be made. Forty-eight percent of hospitals had policies allowing physicians to write orders limiting treatments other than resuscitation, but only 8 percent had written protocols defining how these decisions should be made (133).

A similar survey of nursing homes in Minnesota in 1984 found that 66 percent had policies allowing DNR orders; 73 percent had policies allowing limited treatment orders; and 18 percent had neither. Very few facilities had written protocols defining either the content of DNR and limited treatment orders or procedures for deciding on such orders (134).

Some nursing homes have formal procedures for ascertaining residents' treatment preferences. At one Baltimore facility, for example, the staff determines within the first week after admission whether the resident is capable of participating in decisions about his or her care. Soon thereafter, decisionally capable residents are asked:

> While you are here, there may come a time when you become too ill to communicate with us about your medical care. Are there any specific instructions you might want us to follow at such a time? (109).

Resident responses provide a basis for further discussion of treatment preferences. These are reviewed every 2 months and whenever there is a change in the resident's condition. For those who are not capable of decisionmaking, families are involved, but not until a treatment decision is needed, because the staff believes that families should not have to make these decisions without specifics on which to base them. A multidisciplinary team is available to assist patients, families, or staff in these decisions if needed (109).

Recently, some nursing homes have begun asking residents on admission or later in their stay whether they want to execute a living will or durable power of attorney. At the Hebrew Home of Greater Washington in Rockville, Maryland, for example, social workers are meeting with groups of residents who are considered decisionally capable to talk about living wills and durable powers of attorney. Those who express interest are approached later individually to determine whether they want to execute such a document (63).

Institutional Ethics Committees

Institutional ethics committees are multidisciplinary groups established within a hospital or nursing home to address ethical dilemmas that arise in the facility (45). Ethics committees were largely unknown in this country prior to 1976, when the New Jersey Supreme Court in its decision on the Quinlan case cited an article about ethics committees by Karen Teel (184) and said that life-sustaining treatment could be withdrawn if an ethics committee agreed that there was no possibility of Karen Quinlan ever returning to a "cognitive, sapient state" (88). Despite this statement of the Court, few hospitals established ethics committees (45).

Impetus for the establishment of ethics committees came in 1983 and 1984 as a result of three developments: 1) a case in Los Angeles in which two physicians were charged with murder for withdrawing intravenous nutritional support from a comatose patient (see ch. 3); 2) endorsement of ethics committees in the President's Commission report, *Deciding to Forego Life-Sustaining Treatment* (153); and 3) publication of Federal regulations on treatment of handicapped infants that strongly endorse the establishment of infant care review committees (45). It is estimated that half to three-quarters of all hospitals now have an ethics committee (44,68), and some nursing homes have ethics committees (226). (See ch. 3 for a discussion of the functions of ethics committees and differences of opinion about their role vis-a-vis the legal system).

The Baby Doe Regulations

From 1982 to 1986, controversy about the appropriate role of the Federal Government in decisions about life-sustaining treatment for individual patients was focused on the Baby Doe regulations, described below. Some observers suggested that if these regulations were upheld in court, similar regulations for elderly people, sometimes referred to as "Granny Doe" regulations, might be forthcoming (18,139). Since the Baby Doe regulations were based on Section 504 of the Handicapped Rehabilitation Act of 1973—legislation that forbids discrimination against handicapped persons of all ages in programs that receive Federal money—similar regulations for elderly people were certainly a possibility.

The Baby Doe regulations based on the Handicapped Rehabilitation Act of 1973 were struck down by the U.S. Supreme Court in June 1986. New Baby Doe regulations based on 1984 Amendments to the Child Abuse Prevention and Treatment Act are now in effect. A brief review of the regulatory and legislative history of the Baby Doe regulations is provided here because of its relevance to questions about the potential role of the Federal Government in treatment decisions for elderly people.

In April 1982, a baby was born in Bloomington, Indiana, with Down's syndrome and esophageal atresia, a defect that prevents normal feeding. His parents refused consent for corrective surgery. A circuit court judge upheld the refusal, the Indiana Supreme decided not to intervene, and the baby died. A month later, the Reagan Administration notified hospitals that Section 504 of the

Rehabilitation Act of 1973 required them to provide life-sustaining treatment for handicapped newborns (139,161).

In March 1983, DHHS proposed several procedures to implement Section 504 of the Rehabilitation Act of 1983. They included: a requirement that hospitals post notices warning against "discriminatory failure to feed and care for handicapped infants" (61); a toll-free number—the Baby Doe Hotline—to allow anyone to report suspected denial of treatment to newborns to the Federal Office for Civil Rights; and "Special Assignment Baby Doe Squads" to investigate such reports (139).

Health care, medical, and nursing associations strongly opposed the procedures, and they were subsequently struck down, revised by DHHS, and reissued in July 1983. In response to continued criticism by professional groups, DHHS revised the regulations again and reissued them in January 1984. The new regulations, which encouraged hospitals to establish infant care review committees as a first forum for review of treatment decisions were less objectionable to health care professionals (139).

Meanwhile, in New York in October 1983, another baby, Baby Jane Doe, was born suffering from spina bifida and other impairments. Her parents refused surgery to enclose her spinal column, and an unrelated individual brought suit to have the surgery done. A lower court authorized the surgery, but that order was reversed by the appellate court. Nevertheless, DHHS sought access to Baby Jane Doe's medical records to determine whether there had been a violation of the Baby Doe regulations.

In 1984, the U.S. Court of Appeals for the Second Circuit affirmed lower court decisions that denied the Federal Government access to the medical records. The Court concluded that Baby Jane Doe did not meet the definition of "handicapped individual" in the Rehabilitation Act of 1973 and that the act was never intended by Congress to authorize Federal intervention in individual treatment decisions (16,18).

The Federal Government did not appeal this decision, but the American Hospital Association, the American Medical Association, and other groups used it to appeal the Baby Doe regulations. The regulations were struck down in June 1984—a decision that was affirmed by the U.S. Supreme Court in June 1986 (16,18).

In the meantime, Congress had passed the 1984 Amendments to the Child Abuse Prevention and Treatment Act. The amendments define medical neglect to include withholding "medically indicated treatment" from "disabled infants with life-threatening conditions" and require State protective service agencies that receive Federal child protective service grant funds to investigate reports of medical neglect, so defined. In April 1985, DHHS issued new regulations, also referred to as Baby Doe regulations, to implement this legislation (139). Because the new Baby Doe regulations are based on legislation that applies only to children, they could not be extended to cover treatment of elderly persons. Federal legislation like the Child Abuse Prevention and Treatment Act but for elderly people remains a possibility, however.

Hospice

Hospice programs provide palliative or supportive care for terminally ill people, and thus are an alternative to the use of life-sustaining technologies. The first hospice was established in this country in 1973, and there are now about 1,500 hospice programs (142). Hospice is a concept, not a setting, and although most hospice programs provide services to people at home, many also provide inpatient care in a hospital, nursing home, or freestanding unit.

Hospice programs emphasize patient comfort rather than curing or controlling disease. Alleviation of pain is a primary objective, and patients' emotional and spiritual needs are addressed as well as their physical needs. Care is generally highly individualized, and families are considered part of the unit of care. Care is provided by a multidisciplinary team, including nurses, social workers, home health aides, physicians, and others. Volunteers are often trained to provide counseling, emotional support, and other services (57).

Since 1982, Medicare has included a hospice benefit for enrollees who choose this type of care. The patient's physician must certify that the patient is terminally ill—defined in Medicare regulations to mean that the person's life expectancy is 6 months or less. While covered under the hospice benefit, an individual waives some other Medicare benefits, but he or she may revoke the hospice election at any time. Medicare reimbursement to hospice programs is based on the cost of care for each patient, but there is a cap on the average cost of care for all beneficiaries (188).

Many hospice patients are elderly. The National Hospice Study, a study of 13,000 patients cared for in hospices between 1980 and 1982, found that 35 percent were age 65 to 74, and another 30 percent were over age 75 (71). The same study found that 94 percent of the hospice patients had terminal cancer. The large percentage of cancer patients in hospices occurs in part because it is easier to diagnose cancer patients as terminally ill and to predict their life expectancy than to predict the life expectancy of persons with other conditions (170). Anecdotal evidence suggests that people with organic dementias, such as Alzheimer's disease, are seldom admitted to hospice programs (221).

Many hospice patients, their families and friends, and hospice staff point out the tremendous value of hospice programs in helping patients and families face terminal illness and cope with the difficult physical and emotional aspects of dying (41, 227). Without questioning the positive effects of hospice for some patients, observers have raised questions about several aspects of the hospice concept and its implementation that are relevant to this report.

First, some observers argue that hospice practices cause some terminally ill people to die sooner than necessary because hospice patients forgo life-sustaining treatments that might extend their lives and because hospice programs use medications that may shorten patients' lives. In addition, because diagnosis is uncertain, it is suggested that some hospice patients may have curable conditions that are missed because they have decided in favor of palliative care only (67). Advocates of hospice care argue in response that the benefits of this approach for the great majority of patients far outweigh these considerations.

Second, some research suggests that the care received by patients in some hospice programs may not differ significantly from conventional care. In one study, for example, terminally ill cancer patients treated in a hospital-based hospice program were compared with similar patients who received conventional care. The hospice patients reported more satisfaction with their care than the other patients, but there was little difference between the groups in number of invasive and curative treatments and no significant difference in depression, anxiety, or the frequency and intensity of pain reported by the patients (93,94). In contrast, the National Hospice Study found that hospice patients received significantly fewer intensive medical interventions and diagnostic tests than conventional care patients; there were few differences between the two groups in pain and other symptoms accompanying terminal illness or in patient satisfaction with care, however (71).

Many people argue that hospice care is less expensive than conventional care. Some studies support this contention, and others do not. Whether the cost of hospice v. conventional care is an important consideration in deciding whether hospice care should be available as a treatment option is another point of disagreement. In this context, many people argue that it is inappropriate to consider the cost of care and that the important considerations are how to provide appropriate medical care (67) and/or how to minimize patient suffering.

THE COST OF CARE

Total health care expenditures in the United States (including both acute and long-term care expenditures) constitute about 11 percent of the Nation's gross national product (GNP)—among the highest levels in the world. In 1984, these expenditures amounted to more than $380 billion, the equivalent of about $1,600 per person. Expenditures have increased dramatically in recent decades, whether measured in actual dollars, in spending per capita, or as a proportion of the GNP.

In 1960, for example, total health care expenditures constituted only 5.3 percent of the GNP, $26.9 billion, and $146 per capita (192).

This growth in health care expenditures has raised questions about the proportion of national resources allocated to health care and about how health care dollars are allocated among different age groups and different types of care. With regard to the latter question, the following figures are frequently cited:

- Health care expenditures for the Nation's 29 million elderly persons account for about one-third of all health care expenditures, although the elderly constitute only about 11 percent of the population.
- Medicare expenditures (which are primarily for hospital and physician services) are concentrated in a small proportion of users. In 1982, for example, 1 percent of Medicare enrollees over age 65 accounted for 20 percent of all Medicare expenditures, and the top 5 percent of Medicare enrollees over age 65 accounted for more than 50 percent of Medicare expenditures (162).
- Medicare expenditures are concentrated in the end of life. The 5.9 percent of Medicare enrollees who died in 1978, for example, accounted for 27.9 percent of all Medicare expenditures: 30 percent of this was spent for care in the last 30 days of life, 46 percent for care in the last 60 days of life, and 77 percent for care in the last 6 months of life (119).
- Finally, a small proportion of persons who die incur very high Medicare expenses in the last year of life. Three percent of elderly Medicare enrollees who died in 1978 had Medicare expenditures of over $20,000, and 1 percent had expenditures over $30,000 (119).

These figures are often cited to suggest that the Nation spends too much on expensive medical care for elderly people, especially in the end of life. This expensive care is assumed to include "heroic measures," such as the life-sustaining technologies discussed in this report, and it is implied, and sometimes stated openly, that such care is wasted on people who are going to die anyway. It is also sometimes suggested that public resources now spent on expensive treatment for elderly people who are going to die anyway should be spent instead on preventive health care, medical care for younger people, improvements in long-term care for elderly people, or other public programs, such as education.

This section discusses the cost of care in the end of life and provides brief background on several related topics—determining health care costs, how technology affects costs, public programs that pay for health care for elderly people, and the concept of a "right to health care."

Determining Health Care Costs

Determining health care costs is difficult because of the many components that make up total costs and the ambiguous relationship between costs, charges, and expenditures for health care. Health care costs can include direct, indirect, and intangible costs. Direct costs are the value of products and services related specifically to the diagnosis or treatment of an illness. They include medical costs, such as nursing personnel, equipment, and medical supplies, and nonmedical costs (e.g., travel to a physician's office, special foods, or homemaker services). Indirect costs of health care are the value of lost opportunities, such as lost income, related to mortality or morbidity. Intangible costs include pain, suffering, and other outcomes of illness that are difficult to measure. Information about the costs of medical interventions is often difficult to obtain, and even when costs are reported, they rarely include indirect or intangible costs or even nonmedical direct costs.

Frequently, the only available information about the cost of medical interventions is charges (i.e., billed amounts) or expenditures (i.e., payments). But charges and expenditures may not accurately reflect costs for a variety of reasons not discussed here. Sometimes only Medicare expenditure data are available, but they do not include the Medicare deductible and coinsurance paid by the beneficiary, charges for Medicare-covered products and services that are greater than allowed charges, or the cost of products or services that are not covered by Medicare, including outpatient drugs and most nursing home care. Information in this report about costs, charges, and expenditures should be viewed with these shortcomings in mind.

The Cost of Care at the End of Life

As indicated, a significant percentage of Medicare expenditures is for elderly people at the end of life. Research shows that expenditures for persons who die are significantly greater than expenditures for persons who do not die (128,210,211, 212). One frequently cited study (119) found, for example, that Medicare expenditures in 1978 were six times higher for elderly enrollees who died than for enrollees who did not die in that year.

These figures compare Medicare expenditures for people who died with expenditures for all other elderly Medicare enrollees, some of whom were not sick and some of whom used no Medicare-covered services. In general, people who die have been sick, and health care expenses are higher for people who are sick than for people who are not. This obvious point is sometimes forgotten in discussions about the cost of care at the end of life.

Ninety-two percent of Medicare enrollees who died in 1978 used some Medicare-covered services in their last year of life compared to only 58 percent of Medicare enrollees who did not die (119). When expenditures for these two groups of users are compared, Medicare expenditures are four times higher for those who died than for those who did not die (instead of six times higher as cited above). Thus, *part* of the explanation for higher Medicare expenditures for those who died is the greater likelihood that they used at least some Medicare-covered services in their last year of life.

The relatively high percentage of all health care expenditures for elderly people (29 percent) compared to their proportion of the population (11 percent) is also explained at least in part by the higher prevalence of illness and death among elderly people. In 1984, for example, nearly 70 percent of all decedents were elderly (216). Some people conclude from these arguments that high Medicare expenditures for elderly people who are sick or dying are reasonable and to be expected and that Medicare was enacted precisely to pay for hospital and other acute care for such people.

Although it is true that elderly people who die incur greater Medicare expenditures than those who do not die, most elderly people who die do not incur high Medicare expenditures. Data presented in table 2-4 show that 69 percent of elderly Medicare enrollees who died in 1978 incurred less than $5,000 in Medicare expenditures and 45 percent incurred less than $2,000 in Medicare expenditures. Moreover, average Medicare reimbursement for persons who die decreases with age. In 1978, average reimbursement for persons over 85 who died was only about half the average reimbursement for persons age 67 to 69 who died (119).

No data are available to determine how much is spent on life-sustaining treatments for elderly persons who die, but high health care expenses, especially hospital expenses, are sometimes assumed to indicate the use of life-sustaining treatments. Further inspection of the data in table 2-4 shows that among the approximately 10,000 elderly persons who received more than $30,000 in Medicare reimbursements in 1978, 5,000 lived, and 5,000 died in that year. Among all those who received $20,000 to $29,999 in Medicare reimbursements, 20,000 lived, and 19,000 died. If high Medicare expenditures do indicate the use of life-sustaining treatments, these data suggest that at least half of those who received such treatments lived.

Even so, it could be argued that the expenditures for people who died were wasted. Scitovsky points out, however, that persons who die can only be identified in retrospect:

> It is easy enough, of course, to designate a patient as terminal or as dying *retrospectively* but an entirely different matter to do so *prospectively*. Despite the enormous advances of modern medicine in the past 50 years or so, medical prognosis is still highly uncertain. In fact, modern medicine, by vastly increasing the armamentarium at the physician's disposal, may well have increased the difficulty and uncertainty of medical prognosis compared to the days when the physician could do little more than give moral support to the sick. Today, predicting imminent death with any degree of certainty is difficult in the case of most patients, and predicting death 12 or 6 or even 3 months in advance well-nigh impossible (170).

When the cost of care for persons in the last year, 6 months, or 30 days of life is reported in the media, it is sometimes erroneously assumed

Table 2-4.—Medicare Reimbursements for Decedents in Their Last Year of Life and Survivors in 1978

	Survival status			
	Decedents		Survivors	
Reimbursement interval	Number of enrollees in thousands	Amount of reimbursements in millions	Number of enrollees in thousands	Amount of reimbursements in millions
Total	**1,142**	**$4,969**	**18,342**	**$13,365**
No reimbursement	89	0	7,679	0
Less than $100	86	4	3,597	159
$100 to $1,999	336	279	5,111	2,917
$2,000 to $4,999	274	919	1,252	3,984
$5,000 to $9,999	217	1,546	516	3,540
$10,000 to $14,999	84	1,024	124	1,485
$15,000 to $19,999	32	552	37	627
$20,000 to $29,999	19	439	20	479
$30,000 and over	5	205	5	173
	Percent distribution			
Total	100	100	100	100
No reimbursement	8	0	42	0
Less than $100	8	([a])	20	1
$100 to $1,999	29	6	28	22
$2,000 to $4,999	24	18	7	30
$5,000 to $9,999	19	31	3	26
$10,000 to $14,999	7	21	1	11
$15,000 to $19,999	3	11	([a])	5
$20,000 to $29,999	2	9	([a])	4
$30,000 and over	1	4	([a])	1

[a] Less than 1 percent.

SOURCE: J. Lubitz and R. Prihoda, "The Use and Costs of Medicare Services in the Last 2 Years of Life," *Health Care Financing Review* 5(3):117-131, 1984.

that their deaths were predictable. But accurate predictions are seldom possible.

The findings of one study conducted in an ICU (53) are relevant to this point. When each patient was admitted to the ICU, a physician estimated the probability that the patient would survive to be discharged from the hospital. Results of the study indicate that 9 percent of admissions ended in the death of the patient, and these patients accounted for 17 percent of all charges. Mean charges for patients given less than a 50 percent chance of survival were twice as high as mean charges for patients given a greater than 50 percent chance of survival. However, among survivors, the highest expenditures were for patients given a low probability of survival. Likewise, among nonsurvivors, the highest expenditures were for patients given a high probability of survival. The researchers concluded:

> Our study confirms the association between high cost and poor outcome, and documents a similar relation between high cost and a poor prognosis . . . . However, these two results do not follow from each other; the relations between prognosis, expenditure, and outcome are more complex than can be appreciated when a study focuses only on nonsurvivors or on subsets of patients with the poorest prognosis or the highest costs.
>
> Among nonsurvivors, the highest charges were due to caring for patients who were perceived at the time of admission as having the greatest chance of recovery. Among survivors, the highest charges were incurred by those thought to have the least chance of recovery. Patients with unexpected outcomes (death for the patient with a good prognosis or survival for the patient with a poor prognosis) incurred the greatest costs.
>
> Our findings emphasize the importance of clinical uncertainty in determining resource expenditures for the critically ill; when the outcome is least expected, the expenditures are greatest (53).

Many analysts have suggested that better information about the expected outcome of treatment for different types of patients could improve clinical decisionmaking. For this reason, OTA commissioned a paper on "Classification Systems for

Decisionmaking for Critically Ill Elderly Patients" and sponsored a workshop on this topic. The consensus of experts at the workshop was that existing classification systems, while valuable for many administrative and research purposes, are not sufficiently precise to be used for individual treatment decisions.[1]

It is frequently said that increased use of expensive life-sustaining treatments for terminally ill patients is responsible, at least in part, for rising health care costs. Scitovsky (170) has argued that the data do not support this contention, and recent analyses of Medicare expenditures for elderly enrollees in 1967, 1975, 1979, and 1982 support her conclusion. The data show that over the past 20 years, average Medicare expenditures for persons who die have increased at about the same rate as Medicare expenditures for persons who survive. According to HCFA analysts, these data indicate that "expensive methods of prolonging the lives of terminally ill patients are not the culprit behind increasing Medicare program expenditures" (162).

The preceding discussion of health care expenses at the end of life is based almost entirely on analysis of Medicare expenditures and therefore only accounts for services that are Medicare reimbursable—primarily hospital and physician services. An important component of the total cost of life-sustaining treatments that is left out of the analysis is the cost of nursing home care. Medicare pays for only about 2 percent of nursing home care in this country, but many severely debilitated and terminally ill elderly persons spend some time in a nursing home, and some die there.

The true cost of nursing home care associated with the use of life-sustaining technologies could be said to include the cost of care for people receiving life-sustaining treatments in a nursing home and the cost of care for nursing home residents who are alive because they ever received life-sustaining treatments in any setting. Some information is available about how many nursing home residents receive each of the treatments OTA studied, but no data are available on the number of nursing home residents who are alive because they have ever received any life-sustaining treatment in any setting.

One retrospective study of medical care expenses in the last year of life for 365 persons cared for by physicians at a California clinic in 1983 and 1984 (171) provides information about the cost of all types of care received by the patients. The study found that the average expense for medical care in the last year of life was $22,597. Sixty percent of this was spent for hospital care; 20 percent for physician services; 13 percent for nursing home care; and 8 percent for home health care.[2] Total average expenses decreased with age, from $27,939 for decedents under age 65, to $25,418 for decedents age 65 to 79, and $17,720 for decedents over age 80. Average expenses for hospital care and physician services decreased with age: average expenses for physician services, for example, were $8,339 for decedents under age 65, $5,098 for those age 65 to 79, and $2,177 for those over age 80. Conversely, average expenses for nursing home and home health care increased with age: average expenses for nursing home care were $326 for decedents under age 65, $1,262 for those age 65 to 79, and $5,407 for those over age 80.

The same study compared medical care expenses in the last year of life for decedents with different levels of functional ability defined in terms of patients' ability to dress, bathe, and toilet themselves, and to transfer from bed to chair independently. Average medical care expenses were significantly lower for persons who were unable to perform any of the functions independently throughout the 12-month period than for persons who were able to perform all four functions independently throughout the 12 months prior to their death (171). Hospital expenses were sharply lower for persons with impaired functional ability than for persons with unimpaired functional ability. Conversely, nursing home and home health care expenses were higher for persons with impaired functional ability. The author concludes:

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[1] Some findings of the paper and workshop are incorporated in this report. The reader is also referred to the commissioned paper that is available from the National Technical Information Service (see app. A).

[2] Percent figures do not sum to 100 percent due to rounding.

> Data on the relationship between functional status and intensity of care as indicated by expenses for hospital and physician services strongly suggest that the patients who got intensive care in their last year of life were persons who were functioning well during this period, whose prognosis was likely to have been good, and who were not the kind of patients a physician would feel justified in "letting die." By contrast, persons who were in poor functional condition received largely supportive care but very little intensive hospital and physician services (171).

When medical expenses for persons of different ages with similar functional abilities are compared, the difference in their use of specific services is striking. Among persons who were able to function independently, for example, those under age 65 had average expenses for hospital care of $40,227, compared to $20,864 for those age 65 to 79 and $12,642 for those over age 80. These figures suggest some implicit rationing by age for hospital care (171).

A 1984-85 study of the last days of life of elderly decedents in Connecticut, sponsored by the National Institute on Aging, will provide further information about the relationship between service utilization and the functional ability of the individual. Results of the study are due to be released in late 1987 (34).

In summary, only a small percentage of elderly people who die incur high Medicare expenditures in their last year of life, and of all Medicare enrollees with high Medicare expenditures, half or fewer die. Thus, what is generally perceived as "the high cost of dying" may be better described as the high cost of medical care for sick people, some of whom live and some die. Over the past 20 years, Medicare expenditures for persons who die have increased at about the same rate as Medicare expenditures for people who survive. Thus, the increase in Medicare expenditures over that time is not due to disproportionate use of expensive life-sustaining treatments for people who die. Finally, the limited available information on all medical expenses in the last year of life indicate that average expenses decrease with age and functional limitations of the patient and that persons with poor functional ability have significantly lower expenses for hospital care but higher expenses for nursing home and home health care than persons with unimpaired functional ability.

How Technology Affects Health Care Costs

Increases in health care costs can result from increases in the number of persons receiving care; wage and price inflation; and changes in service intensity, which includes changes in technology use. There is a widespread impression that new medical technologies are a major cause of rising health care costs. A 1984 OTA report found that increases in service intensity, including the use of new medical technologies, accounted for about one-fourth of the 93 percent increase in per capita hospital costs from 1977 to 1982 and for a smaller percentage of the increase in nonhospital costs over the same period (199).

Clearly the impact of technology on health care costs should not be evaluated in isolation from its effect on quality of care. There is evidence, however, that some technologies are overused and thus raise health care costs without improving quality of care (199). Overuse is sometimes blamed on what is called the "technological imperative," that is, the belief that if a technology exists, it should be used. Other reasons for overuse of medical technologies are: 1) physicians' desire to do as much as possible for their patients; 2) uncertainties about what constitutes appropriate use; 3) increasing specialization within medicine; 4) public demand for sophisticated technologies; 5) competition among hospitals to attract patients and physicians; 6) incentives created by reimbursement policies; and 7) the practice of "defensive medicine"—i.e., overuse of medical tests and procedures to defend against malpractice suits (198).

As discussed earlier, the development and diffusion of medical technologies is strongly influenced by Federal funding for research and by the coverage and reimbursement policies of Federal programs that pay for medical care. Some observers have noted that one way to limit rising health care costs would be to limit the development and/or diffusion of new medical technologies. Yet few people advocate this approach because of its long-range impact on the quality of health care (75,85). Moreover, although many technologies raise health care costs, some reduce costs, particularly those that decrease the need for hospital care (192). At least one expert believes, however, that limiting the development and diffusion of new medical technology may be the only way to control rising health care costs over the long term (169).

Public Programs That Pay for Medical Care for Elderly People

Public programs pay for a substantial proportion of health care expenses of elderly people. In 1981, they accounted for 64 percent of all such expenses. Private insurance and out-of pocket payments accounted for the remaining 36 percent (205).

Medicare is the Federal program that pays for medical services for most persons over 65, some disabled persons under 65, and persons with end-stage renal disease. In 1981, Medicare paid about 45 percent of all health care expenses of elderly people, including about 75 percent of hospital care, 55 percent of physicians' services, and about 2 percent of nursing home care (205).

Medicare has two parts: hospital insurance, Part A; and supplementary medical insurance, Part B. Medicare Part A covers the first 60 days of hospital care after the patient has paid an initial deductible ($520 in 1987) and the 61st to 90th day of hospital care after the patient has paid a daily coinsurance ($130 per day in 1987). Medicare enrollees also have a lifetime reserve of 60 days of covered hospital care, but they must pay a daily coinsurance of one-half the initial deductible ($260 in 1987).

Medicare Part A also pays for up to 100 days of post-hospital nursing home care if the Medicare intermediary determines that the beneficiary meets Medicare's eligibility criteria for nursing home care. After the 20th day, the patient must pay a daily coinsurance ($65 in 1987). In 1984, Medicare paid for an average of 27 days of nursing home care for eligible beneficiaries (189). Home health care, including visits of a nurse, home health aide, speech or physical therapist, or medical social worker, is also covered within strict guidelines. There is no deductible or copayment for home health care. In 1984, Medicare paid for an average of 27 home health care visits for eligible beneficiaries (189).

Medicare Part B benefits include physician services, supplies ordered by physicians, outpatient hospital visits, and durable medical equipment, prosthetic devices, and other medical services and equipment provided outside the hospital. Part B reimburses 80 percent of "reasonable charges" for covered services, and the beneficiary is responsible for the remaining 20 percent, plus an annual deductible ($75 in 1987) and a monthly premium ($17.90 in 1987).

Medicaid is the joint Federal/State program that pays for medical services for low-income individuals of all ages. In 1981, Medicaid paid about 14 percent of all health care expenses of elderly people, including about 4 percent of hospital care, 3 percent of physicians' services, and 45 percent of nursing home care (205).

Medicaid regulations are established by each State within Federal guidelines, and eligibility requirements and covered services vary significantly among the States. In general, however, Medicaid pays for hospital care for the small proportion of elderly people who lack Medicare coverage, private insurance, or sufficient income and assets to pay for their own care. In addition to physician services and nursing home care mentioned earlier, Medicaid also pays for outpatient hospital care, laboratory services, home health care, medical supplies, drugs, and the inpatient hospital deductible for eligible individuals.

There are no deductibles or copayments in Medicaid, but limitations on allowable income and assets restrict eligibility to persons with low income in all States and very low income in some States.

The Veterans' Administration provides hospital care in VA facilities and nursing home care in VA and non-VA facilities for eligible veterans. Home care is provided through some VA medical centers. Veterans with service-connected disabilities can receive medical care through the VA. Veterans without service-connected disabilities who have income below specified levels or who contribute a specified amount toward the cost of their care can also receive medical care through the VA.

Other public programs also pay for some health care expenses of elderly people but are not discussed here because they seldom pay for services related to the use of life-sustaining treatments. As of 1981, public programs other than Medicare and Medicaid but including the VA paid for about 5 percent of all health care expenses of elderly people, including 8 percent of hospital expenses, less than 1 percent of physician services, and about 4 percent of nursing home care (205).

Public Programs and the Concept of a Right to Health Care

Although health care is regarded by many people as a basic necessity and a basic human right, neither the U.S. Supreme Court nor any appellate court has ruled that there is a constitutional right to health care (154). Federal and State statutes that authorize programs to fund health care —e.g., the Medicare, Medicaid, and VA programs just discussed—thereby create entitlement rights to some health care services; that is, the intended beneficiaries of a program are considered to have a legal right to reimbursement for the health care services designated by the statute or by regulations that implement the statute. But this right does not extend to health care services not covered by the statute or regulations that implement it. Thus, for example, elderly persons enrolled in Medicare have a legal right to reimbursement for Medicare-covered services but no legal right to reimbursement for services, such as outpatient prescription drugs, that are not currently covered by Medicare. Likewise, elderly veterans have a legal right only to specific health care services designated by statute and VA regulations.

Individuals who believe they have been denied services that they have a legal right to receive under Federal or State statutes and regulations can appeal through administrative and judicial channels, but such appeals must be formulated within the limits of the statutes and regulations. The fact that an individual believes he or she needs a given health care service or that a physician says the individual needs the service, or even that the service has already been provided is generally not considered to create a legal obligation for a public program to pay for the service unless the individual is eligible and the service is covered under the program's regulations.

In its 1983 report, *Securing Access to Health Care*, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research concluded that:

> Society has a moral obligation to ensure that everyone has access to adequate health care without being subject to excessive burden (154).

The Commission determined that this moral obligation does not create a corresponding moral right to health care for the individual. Furthermore, the Commission determined that the societal obligation to ensure access to adequate health care is not solely or even primarily the obligation of government. Rather it is an obligation of society in general—including individuals; public and private groups; local, State, regional, and national organizations; professional and workplace organizations; and family, kinship, and ethnic groups (154). Nevertheless, the Commission stated that:

> When the (private health care) market and charity do not enable individuals to obtain adequate care or cause them to endure excessive burdens in doing so, then the responsibility to ensure that these people have equitable access to health care resides with local, State, and Federal Governments.
>
> Although it is appropriate that all levels of government be involved in seeing that equitable access to health care is achieved, the *ultimate* responsibility for ensuring that this obligation is met rests with the Federal Government (154).

Some commentators have criticized the President's Commission for its failure to assert a moral right to health care for the individual and for its failure to advocate a legal right to health care (see, for example, Arras, 1984 [20]). These competing positions have been the topic of extensive legal, ethical, and philosophical debate in recent decades. This debate is relevant to many of the issues discussed in this report, including the issue of how to distribute limited health care resources (see ch. 4).

CONTAINING HEALTH CARE COSTS

Concern about high health care costs in general and about public expenditures in particular have resulted in cost-containment measures in all public programs that pay for health care. This section focuses on Medicare's Part A prospective payment system (PPS) because the technologies OTA studied are provided primarily in hospitals. PPS has created increased demand for out-of-hospital care, however, and cost-containment measures in public programs that pay for nursing home and home care are also discussed briefly.

Medicare's Prospective Payment System for Hospital Care

From its inception in 1965 until 1983, Medicare reimbursed hospitals for inpatient care of Medicare enrollees on the basis of the cost of enrollees' care, subject to certain limitations. The Social Security Amendments of 1983 mandated a new hospital reimbursement system, the prospective payment system. PPS uses diagnosis-related groups (DRGs) to classify *patient groups* by particular diagnoses. Each DRG category has a predetermined payment that was set in the beginning to reflect the average charges per patient per hospital stay for treatment of the disease(s) subsumed under it

The 470 DRGs are based primarily on diagnosis, but surgical procedures, patient age (i.e., under or over age 70), comorbidities, complications, and discharge status are also used to define some DRGs. *Comorbidities* are defined as preexisting conditions that, combined with a specific diagnosis, prolong length of stay by 1 day or more in at least 75 percent of cases. *Complications* are conditions that arise during the hospital stay and prolong length of stay by 1 day or more in at least 75 percent of cases. Comorbidities and complications exist in a particular case if a patient with a given primary diagnosis also has specified secondary diagnoses.

In some cases, patients with identical diagnoses are covered by two DRGs; one includes patients who are over age 70 or have comorbidities or complications, while the other includes patients who are under age 70 and have no comorbidities or complications. Reimbursement for the former DRG is higher than for the latter, and patients who are over age 70 are in the former DRG automatically. There is no additional reimbursement for comorbidities or complications for them.

Patients are assigned to a DRG when they are admitted to a hospital. Those who remain in the hospital much longer than the average length of stay or have much higher than average costs for their DRG category are called "outliers." Medicare reimbursement for outliers is based on the marginal cost of care. Reimbursement for length-of-stay outliers, for example, is 60 percent of the appropriate per diem amount. Outlier payment policy has been a controversial aspect of PPS since its inception. Although outlier payments help to defray losses incurred by hospitals in the care of unusually expensive cases, they do not cover the full cost of these cases, nor are they intended to (158).

The purpose of PPS is to reduce Medicare expenditures while maintaining an acceptable level of quality of care and access for beneficiaries. Since hospitals make money on patients whose care costs less than the fixed payment for their DRG and lose money on patients whose care costs more than the fixed payment, PPS creates a financial incentive for hospitals to decrease the cost of treating a patient in a single hospital stay. Strategies hospitals can use to do this include reducing a patient's length of stay, reducing the intensity of services (i.e., number of services provided), and reducing staffing levels (202).

PPS is based on the assumption that some of the services provided by hospitals in the past were unnecessary or were produced inefficiently, and that cost containment can be achieved by eliminating such services without sacrificing quality of care or restricting access to necessary care. It is recognized, however, that the system will have both positive and negative impacts. The potential positive impacts of reduced length of stay and reduced intensity of services include psychological benefits for some patients, reduced use of unnecessary services, and lessened chance of iatrogenic events (infections, drug reactions, or other problems that result from medical treatment). Potential negative impacts include decreased access to and use of necessary services and premature discharge of hospitalized patients (202).

PPS is expected to affect the care of different kinds of patients in different ways, and analysts have identified several groups of elderly patients who may be at risk of reduced quality of care, reduced access to necessary care, or both. They include:

- the oldest elderly (74,202, 215),
- patients with multiple conditions (28,84,131, 156,202),
- severely or critically ill patients (28,176),
- patients with end-stage renal disease (215),
- patients who require nursing home or home health care following hospital discharge (131), and
- the poor elderly (215).

These groups overlap. Common factors among them are the likelihood that patients in each group will remain in the hospital longer or incur higher costs than other patients in the same DRG. Patients in these groups have been called "DRG losers." Since they are relatively easy to identify, some observers fear that some hospitals will refuse to admit them or transfer them to public hospitals, a phenomenon called "dumping"; that they may not receive all the services they need; and that they may be discharged too soon (28,56,176). Other observers argue that professional ethics and fear of malpractice suits will outweigh financial incentives to reduce services for these patients and that high-quality care will be maintained (215).

Average length of hospital stay, number of hospital admissions per 1000 population, and hospital occupancy were all dropping before PPS began and have continued to drop since then, although average length of stay for adults increased slightly in 1986. Hospital staffing levels have dropped since PPS began, and the incidence of patients being transferred to other hospitals has increased (86,158,215). These objective findings have no clear implications for either quality of care or access to care, however. A growing volume of anecdotal evidence and research findings indicate, in addition, that some patients are being discharged "quicker and sicker" (58,121,167,193, 195,206,207).

There are also reports that some hospitals are using the *average* length of stay and *average* cost of care for DRGs as *maximum* lengths of stay and costs (157). Statistical analysis of length of stay data for fiscal year 1986 indicate that this practice, if it exists, is not widespread (40). Nevertheless, since PPS began, an unknown number of patients have been told, improperly, that they had to leave the hospital because their Medicare coverage had run out (157,191,223).

In response to recent polls sponsored by HCFA, the American Society of Internal Medicine, the American Medical Association, and the National Opinion Research Center, one-half to three-quarters or more of the physicians surveyed reported being asked by hospital adminstrators to reduce lengths of stay, diagnostic testing, and medical procedures in general (130). According to polls and anecdotal reports, many physicians believe that such reductions in length of stay and service intensity are reducing quality of care and access to care (14,86,138,233).

Before PPS and on a continuing basis, experts have identified problems in quality of care and access to care that could occur in response to the system (28,174,202). ProPAC, other public and private agencies, and professional associations are monitoring its impact. HCFA is conducting numerous studies to identify and evaluate the effects of PPS (215), but the adequacy of this research has been questioned by OTA, the General Accounting Office, and some congressional committees (193,202,207).

A major problem in evaluating the effects of PPS is the difficulty of defining and measuring quality of care. Ideally, quality of care could be evaluated in terms of patient outcomes, but there are many problems with this approach (202). As one observer has noted:

> Negative outcomes (e.g., death, disability) are inevitable given the current state of the medical art—despite tremendous technologic advances, many diseases still elude a cure. This problem is especially pertinent to those elderly with multiple comorbidities. Therefore, the key to outcome studies is to try to disentangle inappropriate outcomes from those which were unavoidable. Once this task is complete, the negative outcome must be linked with some step or misstep in the proc-

> ess of care. Even in settings of clinical trials, establishing this causality may prove a complex task frought with pitfalls (84).

The Institute of Medicine, OTA, and other public and private agencies are currently studying aspects of the problem of measuring quality of care.

Under PPS, hospitals are required to contract with a peer review organization (PRO) to monitor quality of care and evaluate the medical necessity and appropriateness of admissions, inpatient procedures, discharges, and readmissions (202, 215). PRO reviews can result in reclassification of a case from one DRG to another or in total payment denial. In addition, if PRO reviews indicate a pattern of prohibited actions, the Inspector General can terminate the Medicare provider agreement with the responsible hospital, thus prohibiting any Medicare payments to the hospital (215).

Many questions have been raised about the adequacy of the PRO review process in monitoring quality of care (156). Some observers say that PROs have focused more on cost-containment objectives, such as limiting unnecessary admissions and medical and surgical procedures, than on maintaining quality of care (114,125,202). This focus is changing, however, in response to public, congressional, and administration concern about quality of care.

A variety of other measures to ensure quality of care and access to care have been implemented or are being studied. In response to complaints that some patients were being discharged too soon or told that Medicare would not cover their hospitalization, DHHS mailed a notice to each Medicare beneficiary explaining Medicare discharge regulations and how to appeal a premature discharge (214). In addition, ProPAC and other agencies are studying methods of improving the case-mix formulas on which DRGs are based in order to reduce financial incentives for hospitals to deny or limit care for "DRG losers." Under the current system, patients in the same DRG vary greatly in terms of severity of illness, resource use, and the cost of their care. Yet the hospital receives the same payment for all patients in the same group. Addition of a severity of illness measure to the DRG system has been proposed (28,82,176) and is being studied by ProPAC. DHHS recently proposed dropping age as a patient classification variable in PPS because age is not a good predictor of resource use once patient comorbidities and complications are taken into account (183).

None of the preceding discussion addresses the impact of PPS on life-sustaining technologies directly. Clearly the system is not intended to reduce access to or the quality of such treatments. Available evidence as to its impact is discussed in other chapters.

Analysis of the impact of PPS in general or on specific technologies is complicated by the fact that PPS is only one of the factors changing the health care system. These factors include the supply of physicians, enrollment in HMOs and other health care delivery systems that limit hospital use, the emphasis on price competition in medical care in general, and changes in coverage and reimbursement policies in other public programs that pay for medical care. Separating the impact of PPS from the effects of these other factors is difficult, if not impossible, at present (84,86,202).

Cost-Containment Measures in Public Programs That Pay for Nursing Home and Home Health Care

Earlier discharge from hospitals of sicker patients has increased the demand for post-hospital nursing home and home health care (121,144, 156,167,194,195,215). Yet cost-containment measures in the public programs that pay for these services may be limiting access to them, at least in some parts of the country.

As a result of very restrictive eligibility and coverage policies, Medicare pays for only about 2 percent of all nursing home expenses in this country. Recently, there have been reports of increased denials of Medicare reimbursement for nursing home care due to tighter interpretation of existing regulations by some Medicare intermediaries (143,145).

Prior to PPS, patients who could not be placed in nursing homes remained in hospitals, paid for under the Administrative Days Program. PPS creates strong financial incentives for discharging such patients from hospitals now.

A 1986 survey by the General Accounting Office found that 97 percent of hospital discharge planners reported having problems placing Medicare patients in skilled nursing facilities. More than half of those surveyed reported that the percentage of patients waiting in the hospital for placement in post-hospital care was greater in 1985 than in 1982 (195).

Medicaid pays for about 45 percent of all nursing home care, but because Medicaid patients must contribute their own resources toward the cost of their care, Medicaid actually covers a much higher proportion of nursing home residents—65 to 75 percent nationally (220) and 85 to 90 percent in some States (64). Thus Medicaid policies have a strong impact on access to nursing home care.

In recent years, most States have instituted programs to limit Medicaid nursing home expenditures. These include preadmission screening programs, limitations on reimbursement per case, and certificate-of-need programs that restrict the supply of nursing home beds. As a result of differences between States in these cost-containment measures and other factors not discussed here, access to nursing home care for Medicaid patients varies greatly among States. Nursing home bed supply, that affects access for all patients, varies greatly, from a high of 94 beds per 1,000 elderly persons in Wisconsin to a low of 22 beds per 1,000 elderly persons in Florida (190).

Medicare-covered home health care is limited to patients who are confined to their homes and are in need of skilled nursing care or physical or speech therapy for acute conditions. Long-term home health care needed to maintain patient functioning is not covered. Effective July 1985, new Medicare regulations, intended to decrease expenditures, have been put into effect. National and State surveys and anecdotal evidence indicate a recent increase in denials of home health care claims by Medicare (143,196,208). In 1987, 14 Congressmen, 3 home health care agencies, 17 Medicare beneficiaries, and the National Association of Home Care filed suit in the U.S. District Court against DHHS for "irrational and unexplained coverage determinations which fail to take into account and consideration individual patient needs, the attending physician's opinion, and community medical practice" (182).

WHY FOCUS ON THE ELDERLY?

Concern about the use of life-sustaining technologies for elderly people arises in part from awareness of the increasing size of the elderly population and the possibility that many elderly people may be candidates for life-sustaining treatments. This section discusses the growth of the elderly population and patterns of disease and mortality that make many elderly people candidates for life-sustaining treatments. In addition, some reasons to suspect that decisions about the use of life-sustaining treatments and the outcome of treatment may differ for elderly and younger people are discussed.

Growth of the Older Population

The number of elderly people in this country has increased dramatically in this century and will continue to increase well into the next century, as illustrated in table 2-5. In 1900, there were 3 million people over 65. Now there are about 29 million. By 2010, there will be about 39 million. The elderly population is growing at a faster rate than younger age groups. Thus the percentage of elderly people in the population has also increased—from 4 percent in 1900 to 11 percent now—and is projected to reach 14 percent by 2010 and 22 percent by 2050 (209).

Among those over 65, the older groups (age 75 to 84 and 85 +) are growing at a faster rate than the younger group (age 65 to 74). The group age 75 to 84 is expected to increase from about 7.7 million people now (3 percent of the population) to 12 million in 2010 (4 percent of the population) and 21 million in 2050 (almost 7 percent of the population). The age group 85 +, which is the fastest growing age group in the population, is

Table 2-5.—Growth of the Older Population: 1900 to 2050 (numbers in thousands)

Year	Total population all ages	65 to 74 years		75 to 84 years		85 years and over		65 years and over	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
1900	76,303	2,189	2.9	772	1.0	123	0.2	3,084	4.0
1910	91,972	2,793	3.0	989	1.1	167	0.2	3,950	4.3
1920	105,711	3,464	3.3	1,259	1.2	210	0.2	4,933	4.7
1930	122,775	4,721	3.8	1,641	1.3	272	0.2	6,634	5.4
1940	131,669	6,375	4.8	2,278	1.7	365	0.3	9,019	6.8
1950	150,697	8,415	5.6	3,278	2.2	577	0.4	12,270	8.1
1960	179,323	10,997	6.1	4,633	2.6	929	0.5	16,560	9.2
1970	203,302	12,447	6.1	6,124	3.0	1,409	0.7	19,980	9.8
1980	226,505	15,578	6.9	7,727	3.4	2,240	1.0	25,544	11.3
1990	249,731	18,054	7.2	10,284	4.1	3,461	1.4	31,799	12.7
2000	267,990	17,693	6.6	12,207	4.6	5,136	1.9	35,036	13.1
2010	283,141	20,279	7.2	12,172	4.3	6,818	2.4	39,269	13.9
2020	296,339	29,769	10.0	14,280	4.8	7,337	2.5	51,386	17.3
2030	304,330	34,416	11.3	21,128	6.9	8,801	2.9	64,345	21.1
2040	307,952	29,168	9.5	24,529	8.0	12,946	4.2	66,643	21.6
2050	308,856	30,022	9.7	20,976	6.8	16,063	5.2	67,061	21.7

SOURCE: U.S. Department of Commerce, Bureau of the Census, America in Transition: An Aging Society, Series P-23, No. 128 (Washington, DC: Government Printing Office, September 1983).

projected to increase from about 2 million now (1 percent of the population) to almost 7 million in 2010 and 16 million in 2050 (5 percent of the population) (209).

Life expectancy at birth has increased dramatically from 49 years in 1900 to 74 years in 1981 (209). Most of this gain has been due to increased survival past the high risk period of infancy and early childhood. In 1900, for example, only two-fifths of all babies born alive could expect to live to age 65. Today, more than three-fourths of all babies born alive are expected to reach age 65 (163).

Advances in life expectancy after age 65 have been minimal by comparison. A person who reached 65 at the turn of the century could expect to live another 12 years. Today a 65 year-old can expect to live another 17 years. Of the total gain in life expectancy of 5 years, one-half was acheived between 1900 and 1960, and the other half between 1960 and 1983. Hence it appears that life expectancy at older ages has been increasing at a faster rate in the past two decades than previously.

Patterns of Disease and Mortality

Most older people do not suffer from serious illness and are able to function quite well, but the likelihood that persons will suffer from chronic and acute illnesses increases with age, especially after age 75 or 85. The older population has the highest prevalence of chronic conditions such as heart disease, chronic obstructive pulmonary disease, atherosclerosis (deposits of fatty substances within the arteries, or "hardening of the arteries"), and hypertension (persistently high arterial blood pressure). In turn, these chronic conditions increase the risk of acute medical episodes including heart attacks, respiratory arrests, strokes, and pneumonia (216).

Trends in mortality among all age groups since the turn of the century have shown substantial declines in deaths due to infectious diseases, and in age-specific death rates from heart disease, some types of cancer (malignant neoplasms), and cerebrovascular diseases (strokes). These three diseases are the major causes of death in the elderly (see table 2-6).

In general death occurs at older ages than in the past. In 1984, 70 percent of all deaths occurred in the age group over 65; 24 percent among people age 65 to 74; 27 percent among those age 75 to 84; and 19 percent among people over 85. Since elderly people are at greater risk than younger people of chronic and acute illnesses and death, they are also more likely candidates for life-sustaining treatments.

Table 2-6.—Top Ten Causes of Death, Population Aged 65 and Over, United States: 1980

Rank	Cause of death	Number per 100,000 65 +	Percent of all deaths
1	Heart disease	2,330	44.4
2	Malignant neoplasms	1,011	19.2
3	Cerebrovascular diseases	573	10.9
4	Pneumonia and influenza	178	3.4
5	Chronic obstructive pulmonary diseases	171	3.2
6	Atherosclerosis	110	2.1
7	Diabetes mellitus	99	1.9
8	Accidents and trauma	97	1.8
9	Nephritis and related conditions	51	1.0
10	Chronic liver disease and cirrhosis	37	0.7
All causes		5,252	100.0

SOURCE: National Center for Health Statistics, Division of Vital Statistics, *Vital Statistics of the United States, Vol. II, Mortality*, published and unpublished data.

Reasons Why Decisions About Life-Sustaining Treatments or Their Outcome May Differ for Elderly People

In addition to the size of the elderly population and the likelihood that large numbers of elderly people may be candidates for these treatments, concern about life-sustaining treatments for them arises from the expectation that use of these treatments and their outcome may differ for elderly and younger people. Reasons for this expectation, that could be considered some of the hypotheses for this OTA assessment, are discussed briefly below. They are hypotheses, not conclusions, and findings relevant to them are presented in later chapters.

Since, in general, elderly people have a higher prevalence of chronic disease and decreased physiological reserve, there is reason to expect that life-sustaining treatments will have poorer outcome for them than for younger people.

The greater prevalence of chronic disease among elderly people means that elderly people with life-threatening conditions are likely to have one or more coexisting chronic conditions that tend to complicate their treatment and lead to poorer outcome. In addition, longitudinal investigations such as the Framingham Heart Study, the Duke Longitudinal Studies of Normal Aging, and the Baltimore Longitudinal Study on Aging have established that chronological age generally is accompanied by progressive reductions in "physiological reserve," i.e., the functioning and efficiency of major organs.

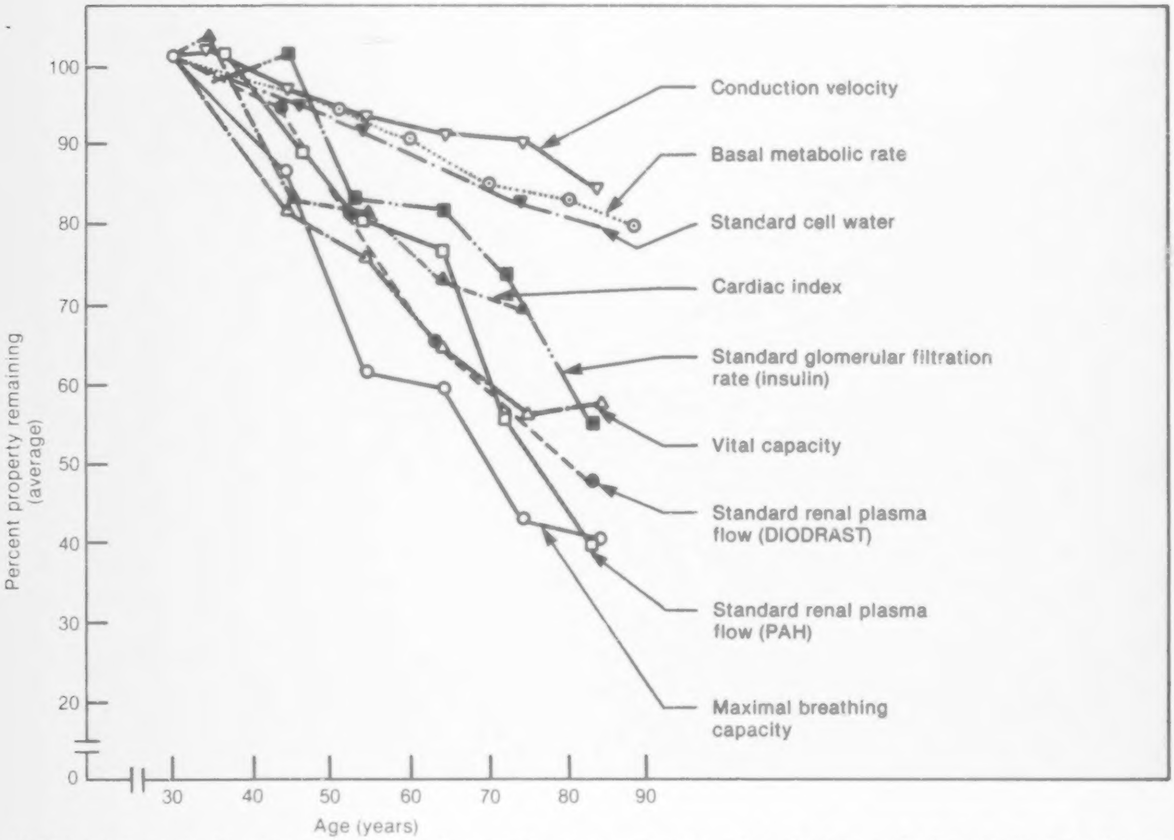
Decreased physiological reserve is different from disease and may not affect an individual's normal functioning. However, it reduces the body's ability to cope with physiological stress, such as acute illness or trauma and, therefore, complicates the treatment of disease and places the individual at greater risk of poor outcome (165). Some changes in average physiological functioning with age are illustrated in figure 2-2.

The rate of reduction in physiological reserve associated with aging varies greatly from one individual to another. In fact, although the physiological status of the older population is certainly poorer as a whole, variation in physiological functioning among individual older persons is greater than in any other age group.

Since elderly people have lived many years and at best have only a limited number of years left, and since they have higher prevalence of chronic conditions and may have lost family and friends, there is reason to expect that their quality of life may be poor and that they may be less willing to accept the burdens of life-sustaining treatment, and more ready to die than younger people.

This hypothesis is seldom stated in full but often appears to underlie some people's attitudes about life-sustaining treatment and elderly people. The elements of the hypothesis—that, on average,

Figure 2-2.—Changes in Physiological Functioning, by Age



SOURCE: N.W. Shock, "The Physiological Basis of Aging," *Frontiers in Medicine: Implications for the Future*, R.J. Morin and R.J. Bing (eds.) (New York, NY: Human Sciences Press, 1985).

elderly people have fewer years left to live than younger people, that they have higher prevalence of chronic conditions, and that many of their relatives and friends may have died—are demonstrably true. The conclusion, however, is not obvious, and OTA is not aware of any data to support it. Anecdotal evidence is contradictory. One observer has commented that older people are more resigned to death than their caregivers (186). Others have commented, however, that elderly people may be more willing to accept a relatively poor quality of life than younger people (77). Generalizations in this area are fraught with difficulties. Nevertheless, the chapters present what is known about differences between elderly and younger people in their attitudes toward maintaining their own lives with the technologies OTA studied.

Because people believe that life-sustaining treatments will have poorer outcome in elderly than younger people, that elderly people have poorer quality of life, and that they may be more ready to die than younger people, and because of a pervasive ageism in our society, there is reason to expect that life-sustaining treatments may be provided less often for elderly than younger people and that, as a result, some elderly people who might benefit from treatment do not receive it.

Negative stereotypes about aging and elderly people among health care providers and the public in general have been well documented (26,39, 120,129,230). When compounded by doubts about the outcome of treatment and doubts about whether elderly people want to live longer. these negative attitudes could result in failure to provide treatment. The report discusses whether age in itself is a factor in decisions about the use of the technologies OTA studied.

Since cognitive impairment is more prevalent in elderly than younger people, there is reason to suspect that decisionmaking may be more difficult for and with elderly people. Cognitive impairment may also affect the decisions that are made and limit the treatments that can be used safely for such patients.

Current estimates indicate that about 1 percent of those age 65 to 74, about 7 percent of those age 75 to 84, and about 25 percent of those over age 85 have dementia (204). In addition, because of the sensitivity of the aging brain to any changes in physical condition, almost all diseases and many medications can reduce cognitive functioning in elderly people (179). As a result, there is reason to expect that more elderly than younger people who are candidates for life-sustaining treatments are cognitively impaired.

Cognitive impairment limits the capacity of the individual to participate in treatment decisions and necessitates involvement of a surrogate decisionmaker in many cases. Families, physicians, and other caregivers may conclude that persons with severe cognitive impairment have very poor quality of life, and they may decide on this basis that some life-sustaining treatments should be withheld or withdrawn. Finally, treatments that require the cooperation of the patient may not be usable for patients who are cognitively impaired. The report discusses what is known about the relationship between a patient's cognitive status and the life-sustaining technologies OTA studied.

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Chapter 3

Legal Issues

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Chapter 3

Legal Issues[*]

This chapter discusses the development and current state of case law and statutes related to decisions about the use of life-sustaining technologies for individual patients. It begins with and is centered around the concepts of self-determination, the patient's right of privacy, the patient's right to refuse unwanted medical treatment, and the implications of these concepts for patients with various levels of decisionmaking capacity. Some persons who reviewed the chapter for OTA suggested that it focuses too greatly on these concepts and should give more emphasis to patients' rights to request and receive treatment and the consequent obligation of society to provide it. These ideas are discussed in chapter 2. A related policy issue—access to care—is discussed throughout the report. This chapter emphasizes the concepts of self-determination, the patient's right of privacy, and the patient's right to refuse treatment because of their greater role in the development of case law and statutes related to decisions about life-sustaining technologies for individual patients.

INTRODUCTION

Laws generally define or reflect what society considers to be the limits of morally appropriate and acceptable behavior. In a complex and technologically advanced society, there are continuous challenges to the foundations that underlie the law. When moral norms and standards of behavior are uncertain, or in conflict, the case law and statutes in different jurisdictions may reflect this diversity of opinion. When consensus has been reached, the case law and statutes of most jurisdictions tend to be similar.

Existing case law and statutes that address medical decisionmaking reflect both consensus and divergence. Societal consensus is reflected in the generally accepted legal principle that adult patients who can understand and appreciate the likely consequences of various treatment options (including nontreatment) are entitled to make their own treatment decisions. Adults are legally presumed to be capable of consent or refusal unless a court declares otherwise.

Although these patient-empowering principles stand firmly etched in our case law and statutes, there is tremendous uncertainty and anxiety among health care providers about what their legal obligations to patients are and what their permissible range of action is. One reason for this uncertainty is that some patients are not capable of making treatment decisions for themselves due to temporary or permanent mental impairment. Case law and statutes in different jurisdictions give different answers to the questions of who is to make decisions, and on what basis, for these patients. A second reason for uncertainty is that technological progress has outpaced the legal process, thus raising questions about how existing case law and statutes apply to new technologies.

Yet another reason for uncertainty is that many health care providers are not aware of or do not fully understand the legal principles, case law, and statutes relevant to medical decisionmaking. This situation is not surprising. Although the law concerning patient's rights has evolved over a long period of time, the first court case to draw national attention to the legal issues involved in withholding or withdrawing life-sustaining treatment from a comatose or terminally ill patient was decided in 1976—little more than a decade ago. Since then, courts in different States have handed down rulings that are contradictory in cases that seem similar from the point of view of health care providers. Many of the contradictions have been resolved as lower court rulings have been appealed and sometimes overturned by higher courts, and the areas of agreement and consistency among different States are growing. Nevertheless, it is difficult for busy health care providers to keep up with changing case law and statutes. It is also difficult for nonlawyers—and even for lawyers at times—to understand the implications of existing case law and statutes for individual treatment decisions (62).

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[*] This chapter is based on several OTA contract reports: Lisa J. Raines, J.D. "Life-Sustaining Technologies for Elderly People: The Legal Issues" (January 1987); Connie Zuckerman, J.D., "Life-Sustaining Technology and the Elderly: The Legal Issues" (June 1986); and George J. Annas, J.D., M.P.H., and Leonard H Glantz, J.D., "Withholding and Withdrawing of Life-Sustaining Treatment for Elderly Incompetent Patients: A Review of Court Decisions and Legislative Approaches" (December 1985)

This chapter describes the legal principles, case law, and statutes related to decisions about the use of life-sustaining medical technologies—particularly as they apply to elderly people. It describes the development of the law and its present state, discusses areas of controversy and criticism, and considers the implications of relevant legal principles for patients and caregivers. The chapter does not discuss statutes or government regulations that pertain to reimbursement for medical care or licensing and certification of health care providers and facilities—both of which are discussed in other chapters of the report.

LEGAL CONCEPTS THAT EMPOWER INDIVIDUAL PATIENTS

The Common Law Right of Self-Determination

American case law has long recognized an individual's right to make certain personal choices. As early as 1891, in *Union Pacific Railway Co.* v. *Botsford*, the U.S. Supreme Court endorsed the fundamental right of self-determination:

> No right is held more sacred or is more carefully guarded by the common law than the right of every individual to the possession and control of his own person, free from all restraints or interference by others, unless by clear and unquestionable authority of law (110).

The right of self-determination was first clearly applied to medical decisionmaking in a 1914 opinion by Justice Cardozo in the New York case *Schloendorff* v. *New York Hospital*:

> Every human being of adult years and sound mind has the right to determine what shall be done with his own body (101).

A strong and explicit restatement of this right appeared in the 1960 Kansas case *Natanson* v. *Kline*:

> Anglo-American law starts with the premise of thoroughgoing self-determination. It follows that each man is considered to be master of his own body and he may, if he be of sound mind, expressly prohibit the performance of life-saving surgery, or other medical treatment (85).

The individual's right of self-determination is now firmly rooted in American case law and statutory law. It is one of the basic concepts underlying a patient's right to be informed about and to consent to or refuse proposed medical treatments.

The Constitutional Right of Privacy

The concept of a constitutional right of personal privacy was first articulated in an 1890 Harvard Law Review article in which Louis Brandeis and Samuel Warren discussed the importance of the "principle of . . . an inviolate personality" (114). Later, while serving on the U.S. Supreme Court, Justice Brandeis further championed this notion, when he wrote in a dissenting opinion that has since become the prevailing view:

> The makers of our Constitution recognized the significance of man's spiritual nature, of his feelings, and of his intellect. They knew that only part of the pain, pleasure, and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men (88).

The "right to be let alone," also called the "right of privacy," is not explicitly articulated in any of the provisions of the Constitution. It is generally considered to emanate from the penumbra of several of the guarantees of the Bill of Rights, including: the First Amendment right of association, the Fourth Amendment right to be secure against unreasonable searches and seizures, the Fifth Amendment right against self-incrimination, the Ninth Amendment protection of rights not explicitly enumerated in the Constitution, and the Fourteenth Amendment guarantees of liberty.

In recent years, the U.S. Supreme Court has held that the right of privacy protects individuals from governmental intrusion in fundamental and personal medical decisions. This right has been the constitutional basis used by the Court to protect private individual decisions ranging from the use of contraceptives, in *Griswold* v. *Connecticut*, 1965 (40); to the termination of pregnancy through abortion, in *Roe* v. *Wade*, 1973 (96); to the refusal of psychotropic medications by those confined in mental institutions, in *Mills* v. *Rogers*, 1982 (82).

The Supreme Court has not addressed the question of whether the constitutional right of privacy includes a right to refuse life-sustaining medical treatment. Several State courts have held that it does, however. In 1976, the New Jersey Supreme Court held in *In re Quinlan* that the right of privacy "is broad enough to encompass a patient's decision to decline medical treatment under certain circumstances, in much the same way as it is broad enough to encompass a woman's decision to terminate pregnancy under certain conditions" (52).

Eighteen months later, in *Superintendent of Belchertown State School* v. *Saikewicz* (109), the Massachusetts Supreme Judicial Court concurred that the right of privacy includes a right to refuse life-sustaining medical treatment. Since the *Saikewicz* case, several other courts have also permitted patients to refuse life-sustaining treatment as an exercise of their right to privacy (see, for example, *In re Colyer*, 1983 [45]).

Neither the constitutional right of privacy nor the common law right of self-determination is absolute. Generally, as discussed later in this chapter, several societal interests have been found to potentially override these rights. It is rare that these state interests are so compelling as to trump the patient's decision, however, and in most cases, the right of privacy and the right of self-determination support the ability of patients to make personal medical decisions (118).

INFORMED CONSENT TO TREATMENT

Development of the Doctrine of Informed Consent

Early American common law (and medieval English common law from which our legal traditions are derived) considered any harmful or offensive nonconsensual touching a "battery" for which monetary damages could be sought in a court of law. Physicians' efforts to heal patients through physical contact such as surgery were considered "touchings." A physician who did not obtain a patient's consent prior to the touching could be held liable for battery, even if the physician had performed an appropriate procedure and had done so carefully (118).

Although a physician was not permitted to obtain a patient's consent through deceptive methods, he or she was not required to give the patient more than a superficial description of the impending procedure and its likely consequences. The law at first focused narrowly on the fact of a nonconsensual "touching" or intervention, rather than on whether the patient truly understood what was being proposed. Even in the famous 1914 *Schloendorff* case (101), in which Justice Cardozo extolled the right of adults to determine what is done with their own bodies, the court was not concerned about the information that individuals needed to exercise this right (118).

The common law right of self-determination means little, however, if health care providers have no obligation to disclose information necessary for patients to thoughtfully exercise the right. The patient's need for information is especially acute in the case of new treatments and procedures that not only present more options and benefits but also are more complex and may be associated with greater risk.

In the late 1950s, the physician's legal duty to obtain a patient's consent was broadened to include an obligation to disclose relevant information so that a patient could make an intelligent decision as to whether to give or withhold consent to treatment. If the doctor obtained a patient's consent without first adequately explaining the procedure, he or she could avoid liability for battery (since the "touching" was technically consensual) but still be liable for medical malpractice (118). (Medical malpractice is a form of negligence defined in the law as conduct that falls below the acceptable professional standards and causes injury to the patient.) If a patient would have withheld consent had he or she known all of the relevant facts, then any injury resulting from the treatment could result in a judgment of malpractice.

Standards for Informed Consent

The first case to use the phrase "informed consent" publicly was the 1957 California case *Salgo v. Stanford University Board of Trustees* (99), but it was the landmark 1960 Kansas case *Natanson v. Kline* (85) that fully articulated the notion of a standard of care with regard to disclosure of information. The Kansas court, concerned about imposing too onerous a burden on physicians, limited the duty of physicians to inform to "disclosures which a reasonable medical practitioner would make under the same or similar conditions." This standard, known as the "professional practice" or "reasonable physician" standard, has been adopted by the majority of States. Under this standard, the extent of appropriate disclosure is viewed as a medical question requiring a physician's expertise to answer. In malpractice litigation, when the professional practice standard is applied, the plaintiff must prove the prevailing standards of medical practice in the community by the testimony of a medical expert. (In Colorado, however, once the plaintiff shows a failure to disclose, it is the physician who must prove that his or her conduct conforms to community standards [see *Hamilton v. Hardy* [41]).

The professional practice or reasonable physician standard has been criticized for perpetuating the custom of many physicians of disclosing very little information before seeking a patient's consent. The ancient Hippocratic texts told physicians to "perform [duties] calmly, concealing most things from the patient while you are attending to him" (59). Some people believe that this view still infuses medical education and practice (63,64).

Three cases decided in 1972, *Canterbury v. Spence* (24), *Cobbs v. Grant* (26), and *Wilkinson v. Vesey* (115), rejected the professional practice or reasonable physician standard and adopted a "reasonable patient" standard. In *Canterbury v. Spence*, the U.S. Court of Appeals for the District of Columbia declared:

> To bind the disclosure obligation to medical usage is to arrogate the decision of revelation to the physician alone. Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves (24).

The court outlined a "reasonable patient" (or "materiality") standard requiring the physician to disclose all information that would be considered by a reasonable patient as material to the patient's decision. Materiality was to be judged not from the subjective perspective of a specific patient but rather from the objective perspective of "a reasonable person, in what the physician knows or should know to be the patient's position" (24).

In *Cobbs v. Grant* (26), the California Supreme Court also adopted the reasonable patient standard, noting that the effect of the professional practice rule had been to give physicians absolute discretion in making (or not making) disclosures. In *Wilkinson v. Vesey* (115), the Rhode Island Supreme Court held that "the patient's right to make up his mind should not be delegated to a local medical group, many of whom have no idea as to his informational needs."

Some commentators consider the reasonable patient standard to be more progressive than the professional practice standard (37,77), but the reasonable patient standard remains the minority rule. The principal difficulty with this standard is that it provides little guidance to the physician. What a reasonable patient would need to know is not always easy to determine, and physicians who have made judgments on this basis have later found that their decisions do not always coincide with a jury's evaluation. A major reason for this variance is the 20/20 hindsight of juries. A risk of serious injury is likely to appear far more material after the patient has suffered the injury than before. In 1980, in *Woolley v. Henderson* (117), a Maine court explicitly rejected the reasonable patient approach for this reason. Other courts have rejected the reasonable patient standard on grounds that medical expertise is required to answer questions about the adequacy of disclosure (see, for example, *Bly v. Rhoads*, 1976 [15]). Since 1972, the trend among courts that have considered the issue has been to adopt the professional practice standard (77,90).

Under either the reasonable patient or professional practice standard, it is generally agreed that in order to fulfill the obligation to inform, the physician must at least disclose the diagnosis, the prognosis, the proposed treatment, alternate treatments, the risks and benefits of all options, and the consequences of not intervening at all. The physician should also give the patient an opportunity to ask questions. Generally, the level of disclosure required to avoid malpractice liability is higher in those States adopting the reasonable patient standard than those adopting the professional practice standard.

Exceptions to the Informed Consent Requirement

Exceptions to the informed consent requirement have been recognized for four situations:

1. emergencies when the delay in treatment necessary to obtain a patient's consent would result in significant harm to the patient,
2. unanticipated conditions that arise during surgery when obtaining consent would expose the patient to the risks of a second surgical procedure,
3. "therapeutic privilege" situations when a physician reasonably believes that the patient's mental or physical well-being would be seriously threatened if he or she learned the information, and
4. waiver situations when the patient has clearly expressed a desire not to receive the information.

In the context of this report, it should be noted that exceptions to the consent requirement are frequently required in cases of unanticipated cardiac or respiratory arrest (emergencies). In addition, some people believe that elderly patients are more likely than younger patients to waive a full explanation of their diagnosis, prognosis, treatment options, and potential risks of treatment. This belief is based on evidence that elderly people are somewhat more likely than younger people to be satisfied with the amount of information they receive (90) and that, as a group, they generally have more deferential attitudes toward health care professionals and are more respectful of authority than younger people (65,87).

In practice, waivers of the informed consent requirement are often based on a tacit understanding between the patient and the health care provider rather than on the explicitly stated preference of the patient (61). To ensure that health care providers do not simply assume that elderly or other patients want to waive their right to informed consent, many commentators have suggested that such waivers should be explicitly stated by the patient and should be allowed only in situations where the provider has made clear his or her willingness to discuss the proposed treatment with the patient (6,61,80,90).

Practical Problems in Informed Consent

Disclosing and explaining information so that a patient's consent or refusal is truly informed is a process that requires time, patience, and an ability to communicate on the part of the physician or other health care provider. The fast pace and pressures of modern medical practice, particularly in hospitals, may leave health care providers with little time or inclination to explain complex medical technologies clearly to their patients or to discuss the risks and benefits of alternate treatments. Moreover, some commentators have noted that the educational experience in most medical schools and the process of professional socialization during internship and residency frequently do not prepare physicians to communicate effectively with patients about their illness, its treatment, and the associated risks, benefits, and alternatives (63,64). These problems are exacerbated when health care providers assume, sometimes without evidence, that a patient is not capable of understanding the explanation, or when a patient has a hearing or speech impairment that interferes with communication. Both situations arise more frequently with elderly patients than younger ones.

One study of medical decisionmaking in a hospital and an outpatient clinic (73) concluded that informed consent as it is envisioned in the law—a process in which a physician provides a patient with information and the patient then brings his or her personal preferences and values to bear on the information, makes a decision, and instructs the physician as to how to proceed—is largely absent from clinical practice. That study showed that patients were seldom given information about the risks and benefits of a proposed treatment before a decision about the treatment was made. They were almost never given information about alternate treatments. Some chronically ill patients—notably those on renal dialysis—were well informed about all aspects of their conditions and treatment, and outpatients were better informed than inpatients. However, most patients acquiesced passively in the physicians' treatment decisions without being informed as required by informed consent law.

According to the researchers, the divergence between informed consent as envisioned by the law and the decisionmaking practices observed in this study arises not only from the behavior of physicians but also from the apparent wishes, expectations, and behavior of patients:

> Our findings suggest that even if doctors were acting in the way anticipated by law, decisionmaking would bear little resemblance to the legal model . . . . We have been struck by the fact that overwhelmingly, even when patients are given information about their treatment and treated as if they had decisional authority, they act in a passive manner. When asked, most patients seemed happy with the amount of information they were getting, and even when they wanted more, it was rarely in order to make decisions about treatment. Even when they said they wanted information to make treatment decisions, they often acted as if they would rather have the doctor decide. For the most part, patients were not very interested in much of what was told to them. Even when they were interested in the information, they still often acted as if the final decision ought to be left to the doctor (73).

The researchers in this study suggest that the model of medical decisionmaking that underlies the doctrine of informed consent—i.e., that medical decisionmaking involves one or more discrete decision points at which the treatment options are clear and one can be selected—is invalid in many clinical situations. In actuality, they say:

> Much of the decisionmaking that doctors engage in takes place at a preconscious level . . . Quite early in the process the physician reaches a diagnosis and a decision about the preferable treatment. Seldom does the doctor see a series of alternative possibilities. Rather, for each problem there typically exists a medically preferable treatment, not a series of alternatives from which a patient may choose. It does not seem to the doctor to be a decisionmaking process but simply a question of persuading the patient to accept proper treatment. The decision has been made—by the doctor (73).

The model of medical decisionmaking that underlies the informed consent doctrine may be more relevant for some types of treatments, some treatment settings, and some patient populations than others. The model is most applicable for patients who have a single medical problem for which there are several treatment options (37,73). In contrast, for some critically ill patients receiving multiple treatments in an intensive care unit (ICU), the medical decisionmaking process may be virtually continuous because of the patient's unstable condition and the complex interaction of multiple illnesses and treatments. In such a situation, the model of medical decisionmaking that requires the patient to be informed and to consent to each decision may be almost impossible to apply. Similar situations may arise with some severely debilitated patients who require a series of decisions, each of which can have life-and-death implications. Both types of decisionmaking situations arise with the medical treatments, treatment settings, and patient populations discussed in this report.

One practical question about informed consent law is the validity and necessity of written consent forms. Many observers point out that the goals of informed consent law are not fulfilled when a patient simply signs a preprinted form without prior communication between the patient and the health care provider about the risks and benefits of the proposed treatment, about alternate treatments, and about the patient's wishes. Yet research and anecdotal evidence indicate that many health care providers act as if getting the patient's signature on a consent form constitutes informed consent (37,61,63,73,90).

Legal experts point out that except when consent is needed for patient participation in a research protocol, a written consent form is not legally required (6,61). Moreover, a written consent form may not even constitute legal proof that informed consent has occurred (14,43,61,105). According to two observers, patients who have signed such a form may claim that they didn't really give informed consent:

> (Patients may claim), "I was nervous"; "I didn't understand because the doctor used big, technical words"; "I was in such pain that I would do anything to get rid of it"; "They had already given me a shot so I wasn't clearheaded"; "The nurse handed me this piece of paper at the last minute and I signed it without even looking at it." Such claims are likely to carry extra weight in the mind of a jury that is contemplating the plight of an injured older patient (61).

Although signed consent forms may not constitute proof that informed consent was obtained, they generally create a legal presumption that it was, and shift the burden of responsibility to the patient to prove that it was not (61).

Despite questions about the legal necessity and validity of written consent forms, most hospitals, nursing homes, and other health care facilities require such forms, particularly for surgical and other procedures that are considered invasive.[1] A requirement for a signed consent form does not guarantee that any meaningful communication has taken place between the patient and the health care provider and may sometimes delay the initiation of treatment while the form is signed, witnessed, and noted in the patient's medical record. In cases where the patient is not decisionally capable, obtaining a signed consent form may require locating a surrogate and having that individual come to the hospital or nursing home to sign the form. For these reasons, some physicians who agree in theory that patients or their surrogates should almost always be involved in treatment decisions and who generally discuss such decisions with patients or their surrogates may regard the process of obtaining written consent as burdensome recordkeeping and may, therefore, resent formal requirements for informed consent (37).

Recognizing the legitimacy of concerns about written consent forms does not solve the problem of how to ensure that informed consent takes place. Some observers have suggested that changes in medical education and professional socialization during medical internship and residency are the best solution to the problem (37,63). Others suggest that legal suits by patients who have been harmed as a result of medical interventions for which they did not give true informed consent are another method for changing medical practice (37). Finally, changes in hospital and nursing home policies with regard to written v. verbal consent and specific delineation in such policies of the role of the patient or surrogate in the decisionmaking process might also be helpful.

None of these solutions, however, will address problems that arise because, as discussed earlier, the model of medical decisionmaking that underlies the doctrine of informed consent does not reflect the realities of some clinical situations. Further analysis is needed to identify informed consent procedures that are both valid and meaningful in situations where decisionmaking is virtually continuous due to the critical and unstable nature of the patient's condition.

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[1] Many health care facilities do not require a signed consent form for treatments that do not involve surgery and are not considered invasive, for example, nasogastric tube feeding and antibiotic treatment (see ch. 8 and ch. 9).

THE RIGHT TO REFUSE TREATMENT

The doctrine of informed consent and the case law and statutes that underlie it support the patient's right to refuse treatment (also known as "withholding consent"). In theory, this right is not diminished by the potentially fatal consequences of refusing life-sustaining treatment or by the opposing views of attending health care professionals. (In practice, as discussed throughout this report, physicians and other health care professionals are often very reluctant to withhold or withdraw life-sustaining treatment and sometimes do not recognize or accept a patient's decision to refuse such treatment.)

To exercise the right to refuse treatment, a patient must possess the requisite mental capacity to process the disclosed information and to make a voluntary health care decision. Although most adult patients are either clearly capable or clearly incapable of making such a decision, some patients have questionable or fluctuating decisionmaking capacity. (See later section "Assessing Decisionmaking Capacity in Elderly Patients.")

Like consent, refusal of life-sustaining or any other therapy by a patient should be based on an informed choice, made in a voluntary manner (81). The information needed to make an informed choice has been examined above.

A voluntary choice implies an absence of coercion. Patients and physicians may have different values and goals in the context of health care decisions. The physician is expected to infuse the informed consent discussion with all of his or her professional expertise and experience and to provide advice and opinion accordingly; the physician is not a neutral observer but rather a skilled advocate of a particular position. It is the patient, however, who is legally vested with the right to decide whether to undertake the treatment. If, after full disclosure by the physician, the patient weighs the risks and benefits of a proposed procedure against his or her own individual fears, hopes, and beliefs, and decides to refuse the intervention, then this is a decision that the physician is legally required to accept. In general, however, if a patient's decision violates the physician's convictions, the physician may withdraw from treating the patient as long as the physician makes reasonable efforts to assist the patient in obtaining appropriate continuing care. (See discussion of the societal interest in protecting the ethical integrity of the medical profession below.)

Societal Interests That May Limit the Patient's Right To Refuse Life-Sustaining Treatment

Strong as it may be, the patient's right to refuse medical treatment is not absolute. The law requires that this right be balanced against the interests of society and, in certain very limited circumstances, give way (77).

Four societal interests have been identified by the courts as potentially worthy of causing the court to override a patient's right to refuse treatment:

1. the preservation of human life,
2. the protection of third parties,
3. the prevention of suicide, and
4. the protection of the ethical integrity of the medical profession.

The societal interest in the preservation of human life is based on the fundamental religious and ethical concept of the value of human life in general and the value of each individual's life. This societal interest has been raised as a competing argument in virtually all court cases concerning refusal of life-sustaining medical treatment.

Although the societal interest in preservation of human life is related to the well-being of individual patients, unless some other individual is adversely affected by a patient's decision, the balancing process applied by the courts has always come out in favor of the patient's decision. The patient's objective well-being alone has never been sufficient legal justification to force unwanted medical treatment on a decisionally capable patient (77,118).

In certain cases, there are cognizable third-party interests in the patient's decision to refuse treatment. Particularly when the patient has minor children who would suffer financially or emotionally or who would be abandoned because of the patient's decision to refuse life-saving or life-sustaining treatment, the state, in its *parens patriae* role, may feel compelled to override the patient's health care decision. This societal interest is obviously more relevant to patients who are parents of young children. Few elderly persons fall into this category.

The societal interest in prevention of suicide is based on the value of human life and the corollary that the individual's life has value even if he or she does not recognize it. This societal interest has been raised most strongly in court cases concerning individuals who are decisionally capable and who wish to refuse life-sustaining treatment. It has also been considered, however, in some cases involving patients who are not decisionally capable (see, for example, *In re Quinlan* [52]). In general, the courts that have considered cases of both kinds have concluded that refusal of life-sustaining medical treatment does not constitute suicide (5,118).

Finally, there is the societal interest in the ethical integrity of the medical profession. Some people argue that the traditional role of health care providers, i.e., to use appropriate therapies to cure or ameliorate the effects of disease or injury, could be seriously affected if patients are allowed to refuse life-sustaining treatments; and that health care providers may view themselves as instruments of the patient's death in such circumstances and thereby be demoralized (17). These concerns notwithstanding, established case law explicitly articulates that protecting the ethical integrity of the medical profession does not demand that patients accept whatever treatment physicians propose, particularly if the treatment would be futile or if the patient holds other values (such as bodily integrity or privacy) above the preservation of his or her own life.

Whether health care providers and health care facilities must participate in withholding or withdrawing treatment when such participation violates their own convictions, is a question on which courts have differed. In the 1986 ruling in *Brophy v. New England Sinai Hospital, Inc.* (21), the Massachusetts Supreme Judicial Court ruled that Mr. Brophy's feeding tube could be legally withdrawn but that the hospital he was in could not be compelled to participate in removing the tube and that Mr. Brophy could be transferred to another facility for this purpose. In the 1986 New Jersey case *In re Requena* (53), in contrast, the judge ruled that Mrs. Requena had the right to refuse tube feeding and that the hospital she was in, which had petitioned the court to have her discharged, must allow her to stay without being tube fed.

The case of Elizabeth Bouvia (see box 3-A) illustrates the conflict between the patient's right of self-determination, right of privacy, and right to refuse unwanted treatment, on the one hand, and the societal interests in preservation of human life, prevention of suicide, and protection of the ethical integrity of the medical profession, on the other hand. In the final decision in this case, the California Court of Appeal ruled, as courts have generally ruled, that societal interests are seldom so compelling that they can override the patient's fundamental right to refuse unwanted medical treatment (5,111,118).

Practical Problems in Refusing Treatment

The patient's right of self-determination and right to refuse treatment are of little value if they are not supported in practice. Indeed, the treatment setting and the beliefs and personalities of the parties involved may have as much, if not more, impact on a patient's ability to refuse treatment than the dictates of legal theory.

Hospitals may be overwhelming and intimidating for some patients. They are often large, complicated institutions. Patients are often subject to a steady stream of providers and procedures, some of which are not explained and some of which are ordinarily provided without the patient's explicit consent—for example, medications. Overall, a patient may have little influence over the daily course of events and may perceive a loss of control.

The primary goal of hospitals is the diagnosis and remedy of acute medical conditions, so that patients can return to their baseline functioning. There is a strong institutional commitment to curing disease and preserving life, and sophisticated equipment and highly trained staff are readily available to achieve these goals. The patient who refuses life-saving or life-sustaining interventions stands directly opposed to this institutional commitment.

Box 3-A.—The Elizabeth Bouvia Case

Elizabeth Bouvia has suffered since birth from severe cerebral palsy. As a result, she is quadraplegic and immobile except for slight movements of her right hand and sufficient facial muscle control to eat if spoonfed. Bouvia experiences constant pain from muscle contractions and arthritis, which is partially relieved by morphine. Despite her disability and pain, however, Bouvia is not suffering from a terminal illness, and death from her condition is not imminent.

In 1983, Bouvia admitted herself to a hospital in Riverside, California, and announced her intent to starve herself to death. When this decision was challenged by the hospital staff, she sought a court order to prevent any health care—including nutrition and hydration—without her consent.

Bouvia contended that insertion of a nasogastric tube against her will would violate her common law right of self-determination and her constitutional right of privacy. Physically unable to take her own life, she claimed that she had a right to determine when and how her life would end and that society has an obligation to honor and to assist her in achieving that right.

The hospital's lawyers asserted that there is no statutory, constitutional, or ethical right to commit suicide, nor to enlist the aid of others in so doing. The hospital's medical and nursing staff believed that honoring Bouvia's wishes would be contrary to medical ethics and would have a devastating effect on the morale of other patients. They were also concerned that possible criminal, civil, or license revocation proceedings might result.

The trial court in *Bouvia* v. *County of Riverside* (18) found that Bouvia was mentally capable of making medical decisions and that her decision was rational and primarily reached because of the nature and extent of her physical condition rather than from unhappiness due to nonmedical life situations. Therefore, the court determined, the ultimate issue was "whether or not a severely handicapped, mentally competent person who is otherwise physically healthy and not terminally ill has the right to end her life with the assistance of society." The court concluded that she did not. While recognizing Bouvia's right to terminate medical intervention, the court held this right had been overcome by the strong interests of society to preserve life and prevent suicide.

After losing her case, Bouvia reportedly went to Mexico to seek her death. When she learned that Mexican health care providers were no more sympathetic than those in Riverside, she returned to California and entered a private facility where she remained without incident for over a year. In late 1985, she was admitted to a hospital in Los Angeles, where a "morphine pump" was installed for pain control. Two months later, she was transferred to another hospital (3).

During this period, Bouvia's ability to take in sufficient nutrients by mouth deteriorated. Although she was eating voluntarily, her weight dropped below 70 pounds. To increase her caloric consumption, a nasogastric feeding tube was inserted against her will. Bouvia sought a court order to terminate the tube feeding. In February 1986, the trial court in *Bouvia* v. *Glenchur* (19) denied her petition. Despite Bouvia's testimony that she had not attempted to starve herself since her trip to Mexico and medical evidence suggesting that her liquid diet was medically reasonable, the court held that Bouvia had no right to refuse nasogastric tube feeding because "in the opinion of the medical staff at defendant hospital, plaintiff's refusal would to a reasonable medical certainty directly result in a life-threatening condition."

Bouvia's attorneys appealed. The California Court of Appeal held in April of 1986 that a patient has the right to refuse "any medical treatment or medical service, even when such treatment is labeled 'furnishing nourishment and hydration,'" and that this right exists "even if its exercise creates a 'life threatening condition.'" The court also stated that the "right to refuse medical treatment is basic and fundamental," and is "recognized as a part of the right of privacy protected by both the [California] State and Federal constitutions . . . . Its exercise requires no one's approval" (20).

In its decision, the appellate court clarified that there is no requirement that patients be terminally ill or "imminently" dying before exercise of the right to refuse treatment. (It is estimated that Bouvia could live for 15 or 20 years on tube feeding.) It affirmed that decisions to forgo medical treatment or life support through mechanical means belong only to the patient.

> It is not a medical decision for her physicians to make. Neither is it a legal question whose soundness

> is to be resolved by lawyers or judges. It is not a conditional right subject to approval by ethics committees or courts of law. It is a moral and philosophical decision that, being a competent adult, is hers alone (20).

The court also firmly rejected arguments that physicians have a right to preserve a patient's life against that patient's wishes. "It is incongruous, if not monstrous," the court wrote, "for medical practitioners to assert their right to preserve a life that someone else must live, or, more accurately, endure, for '15 to 20 years.' We cannot conceive it to be the policy of this State to inflict such an ordeal upon anyone" (20).

Finally, the court found that Bouvia's motives for exercising her right to refuse treatment are immaterial. At the same time, it rejected arguments that she is in fact attempting to commit suicide (20).

The difference between the 1983 and the 1986 cases lies in the premises on which the cases were based. In the first case, Bouvia had sought the right to refuse any nutrition at all. Since she could eat enough to live and chose not to, her refusal of tube feeding was viewed as attempting to commit suicide. In the recent case, she sought the right to avoid artificial feeding while voluntarily taking in whatever nutrients she could tolerate. Since she could no longer voluntarily orally consume adequate amounts of food, tube feeding was viewed as "medical treatment" replacing a failed physical function. On that premise, the appellate court found her right to refuse artificial feeding in the second case to be similar to the right to refuse treatment generally.

The appellate court added that it did not "doubt the sincerity of the hospital and medical personnel's moral and ethical beliefs . . . However, if the right of the patient to self-determination is to have any meaning at all, it must be paramount to the interests of the patient's hospital and doctors" (20).

Although the trial judge who initially denied Bouvia's request in February 1986 distinguished the Bouvia predicament from other termination-of-treatment cases by noting that Bouvia could live for many more years with the proper nutrients, the appellate court held that such a distinction was inappropriate:

> In so holding, the trial court mistakenly attached undue importance to the amount of time possibly available to petitioner, and failed to give equal weight and consideration to the quality of life; an equal, if not more significant, consideration.
>
> Here, if force-fed, petitioner faces 15 to 20 years of a painful existence, endurable only by the constant administration of morphine. Her condition is irreversible. There is no cure for palsy or arthritis. Petitioner would have to be fed, cleansed, turned, bedded, toileted by others for 15 to 20 years! Although alert, bright, sensitive, perhaps even brave and feisty, she must lie immobile, unable to exist except through physical acts of others. Her mind and spirit may be free to take great flights but she herself is imprisoned and must lie physically helpless subject to the ignominy, embarrassment, humiliation, and dehumanizing aspects created by her helplessness (20).

In the face of the strong institutional commitments to provide treatment, refusing treatment requires courage and personal force on the part of the patient—qualities that may be difficult for a critically or terminally ill or severely debilitated patient to muster. This is especially true when the patient is intimidated or confused by the situation he or she is in. Moreover, when a patient is wholly dependent on physicians, nurses, and other health care providers for all of his or her physical needs (as a patient may be in a hospital), the patient may be reluctant to risk the caregivers' disapproval or rejection by refusing treatment.

Residents of nursing homes face some of the same practical problems in refusing treatment as hospital patients. Specifically, the daily routine and general atmosphere in some facilities engender extreme dependence and a feeling of loss of control. Moreover, many nursing home residents are not cognizant of their rights to receive information about their condition and treatment and to consent to or refuse proposed interventions. Finally, many nursing home residents are disoriented or memory impaired (at least 63 percent according to the findings of the 1985 National Nursing Home Survey [112]). Even if a resident has the full capacity to make decisions, the staff sometimes assumes that he or she does not (4).

An outpatient setting, such as a physician's office, may be less intimidating than a hospital or nursing home for several reasons. There is often more equality in the relationship between patient and physician in an outpatient setting. An outpatient may be in better health than a hospital or nursing home patient, and his or her overall functioning may be better. The encounter between an outpatient and physician is scheduled in advance and at the patient's convenience, rather than occurring without warning as, for example, when the physician stops by the patient's room in a hospital or nursing home. Finally, if an outpatient is dissatisfied with the information and options presented, he or she can simply leave the physician's office and seek the advice and services of another physician.

This apparent ease for the elderly patient in an outpatient setting is deceptive, however. In particular, it may not be quite so easy for the elderly patient to "shop around" for the most accommodating and respectful caregiver. Many elderly people have low incomes. If a physician does not accept Medicaid, or requires the patient to pay a premium above the Medicare reimbursement rate, that physician is, in effect, unavailable for some elderly patients. Moreover, lack of transportation keeps many elderly patients from leaving one caregiver for another who is less accessible geographically. Thus, even outpatients may experience practical problems in finding a physician who will continue to treat them but accept their refusal of a proposed medical intervention.

Legal Liability for Failure To Recognize the Patient's Right To Refuse Treatment

The only reported case in which health care professionals and health care institutions have been held to be potentially liable for damages for failing to recognize a patient's right to refuse treatment is *Leach v. Shapiro* (70):

> In 1980, Edna Leach, a 70-year-old woman with amyotrophic lateral sclerosis (ALS), was admitted to an Akron, Ohio, hospital because of breathing difficulty. She had a cardiac arrest in the hospital, was placed on a mechanical ventilator and nasogastric tube feeding, and remained in the hospital in a chronic vegetative state (69).
>
> After 4 months, her husband asked her physician to remove the ventilator. The physician refused, and the husband, who was her legal guardian, petitioned an Ohio court for an order to discontinue life support. The court granted the petition in December 1980. The mechanical ventilator was removed in January 1981, and Mrs. Leach died (70).
>
> In 1982, Mrs. Leach's estate petitioned the court for punitive damages for the 159 days she was on life support following her husband's request that the ventilator be removed. The trial court that heard the case dismissed it on the grounds that there was no legal basis for a finding of punitive damages in such a case (70).
>
> The appeals court reversed this decision, ruling that the physician and the hospital could be liable for punitive damages if it could be shown that Mrs. Leach's legal guardian did not give explicit informed consent for the treatment and that Mrs. Leach had previously expressed her wish not to be kept alive on machines. The case was sent back to the trial court for determination of these facts (70).

Prior to the trial, the hospital settled out of court with the Leach estate. At the trial, in which the physician remained a defendant, the judge ruled that there was not sufficient evidence to go to a jury, and the case was dismissed (103).

COMPETENCY AND DECISIONMAKING CAPACITY

The law presumes that adults are competent—that is, all adults are considered to be able to exercise the full panoply of rights afforded to them upon reaching the age of majority. This legal presumption of competence is a global protection that grants individuals the freedom to act in numerous spheres of life.

Not all adults have sufficient mental abilities to make and articulate rational decisions, however. If factual evidence that a patient lacks decisionmaking capacity is presented to a court of the appropriate jurisdiction to rebut the presumption of competency, the patient may be declared "incompetent." Unless there is a formal court challenge to an individual's competency, however, the legal presumption of competency and all the attendant rights it affords remain in effect.

When nonlawyers describe an individual as "competent" in the context of a health care decision, they rarely intend the label to evoke the global legal presumption just described. Instead, they usually mean only that they personally believe the individual has the requisite mental capacity to consent to or refuse a particular medical intervention. Likewise, when nonlawyers describe an individual as "incompetent" in this context, they seldom mean that a court has determined that the individual is incompetent. Rather, they mean that they personally think the individual does not have the requisite mental capacity to consent to or refuse treatment.

In this report, in order to avoid confusion between the two meanings, the words "competent" and "incompetent" are used only in the legal sense. Thus, the word "incompetent" is only used to describe an individual who has been determined by a court to be incompetent. The words "decisionally capable" and "decisionally incapable" are used to describe an individual's mental capacity as determined formally or informally by any individual or group other than a court. Used in this way, the terms competent and decisionally capable are not always synonymous—adult patients can retain their legal presumption of competence while being clearly not decisionally capable in the opinion of their caregivers or families. Likewise, the terms incompetent and decisionally incapable are not necessarily synonymous—adult patients who have been declared incompetent by a court may be perceived by their caregivers or families to be able to participate in a specific health care decision. (Few health care providers would risk following a treatment decision of a patient who has been adjudicated incompetent, though.) Moreover, in some cases, courts have decided that an individual is not capable of making a specific health care decision but have not declared the individual incompetent.

In the reality of medical practice, if a patient consents to a proposed intervention, it is very unlikely that the patient's competency will be challenged, particularly if family members also agree (33,77). If all agree that a proposed intervention promotes the patient's objective well-being, it is in no one's interest to probe the patient's decisionmaking capacity and undermine the patient's presumed competency. People sometimes assume that if "competent," the patient would have chosen the option that promotes his or her objective well-being anyway. In the absence of contrary evidence, no one is likely to challenge this assumption (118).

Thus, refusals of therapeutic or diagnostic procedures that are recommended by a physician trigger most assessments of a patient's decisionmaking capacity (33,90). It is generally agreed that when a patient's choice differs from what is thought to be in his or her objective best interest, caregivers should confirm that the patient is decisionally capable. This is not to say that *because* the patient chooses differently than the physician, the patient is decisionally incapable. But when a patient refuses an intervention that would be lifesaving or medically beneficial, it is prudent to make certain that the patient is accurately informed, acting voluntarily, and able to reconcile this decision with his or her personal values and preferences (33,118).

Assessing Decisionmaking Capacity in Elderly Patients

Although American law presumes, absent a ruling by a court to the contrary, that every adult is capable of consent or refusal of any proposed medical treatment, the reality is that health care providers, family members, and others often assume that elderly people are decisionally incapable. Actions that would not be thought to indicate incapacity in a younger person all of a sudden do indicate it in an elderly person (5). This is not a new problem. The sons of Greek dramatist Sophocles brought a proceeding against him to obtain his property and supported their argument that Sophocles was a lunatic on the basis of his preoccupation with writing his play *Oedipus at Colonus*. In his defense, Sophocles read from the play and asked the jury if it seemed the work of an imbecile. The jury reportedly applauded the reading and declared Sophocles to be of sound mind. One modern legal commentator opines that under contemporary statutes, use of this defense could result in the sons' walking out of the courtroom "in control of his property" (9). Indeed, many States retain "advanced age" as sufficient grounds for appointment of a conservator over one's property. Moreover, until 1976 in California and 1978 in Illinois individuals could be found incompetent merely because they were "old and sick" (9).

Some persons of all ages are clearly incapable of making decisions (e.g., persons who are permanently unconscious) but there are many other persons whose ability to make decisions is not clear. Among the elderly, such persons may suffer from the early stages of Alzheimer's disease or another disease that causes dementia. Although they may be currently capable of making decisions about their medical care, this status is often fluctuating or declining. Alternatively, many acute and chronic diseases and conditions can affect mental ability—usually temporarily. Infections, cardiovascular disease, dehydration, and nutritional deficiencies are a few examples. Persons with any of these diseases or conditions may be currently incapable of making decisions, although it is likely that their decisionmaking capacity will be restored. Pain or fatigue associated with acute or chronic disease and many medications can also cause temporary confusion. Those who assess a patient's mental abilities need to be aware of these effects and their potential impact on the patient's decisionmaking capacity.

Because of the sensitivity of the aged brain to any changes in a person's physical condition, fluctuating cognitive ability may be more common among elderly people than younger people. Persons with fluctuating cognitive ability may appear quite lucid at some times and confused and disoriented at other times. Such patients may be able to make decisions during intervals of lucidity, but if a patient's cognitive ability fluctuates, accurate assessment may take more than one visit. Some experts suggest that when assessment of decisionmaking capacity is being conducted in a nonemergency setting, there should be at least two contacts with the patient on different days (7).

There are no uniformly accepted procedures for determining decisionmaking capacity. In fact, in many clinical settings, patients' cognitive deficits that may affect decisionmaking capacity are not routinely identified (31,38,66,79,89,95). When the need to determine a patient's decisionmaking capacity arises in the context of a proposed diagnostic procedure or therapeutic intervention, the determination is often made quickly and on an ad hoc basis, frequently without any manifest awareness on the part of the physician or other health care provider that it is being made (73).

In hospitals and sometimes in nursing homes, if a patient refuses a proposed intervention, staff may request an evaluation by a consulting psychiatrist. Whether the psychiatrist has the final word on the patient's capacity to make the decision depends on many factors, including the policies of the institution, its sensitivity to the rights of patients, and even the strength of the patient's refusal (118).

Health care providers may turn to family members or in their absence other available parties (such as clergy or close friends) for help in assessing the patient's capacity to make a decision. Those who know the patient best can help to determine whether the patient's articulated refusal is consistent with the preferences and values that he or she has expressed over a lifetime. For example, is the patient's refusal of a proposed amputation consistent with the importance he has previously given to such factors as personal appearance or the ability to walk independently? Perhaps the patient has been an athlete who previously told his loved ones that he would never want to lose his leg, even if his life was in jeopardy (118).

If a patient's decision is in accord with his or her previously articulated values, caregivers may be more inclined to accept it even if there is uncertainty about the patient's decisionmaking capacity. In such a situation, labeling the patient "decisionally capable" permits the caregivers to respect the patient's decision and is consistent with the "empowering" notion that underlies the concept of legal competency (118). In such cases, however, the caregiver must walk a fine line between respecting the patient's right to make decisions and protecting the patient from a harmful decision. If the patient does not possess the mental capacity to process the information necessary to render consent or refusal, then the caregiver's acceptance of the patient's articulated choice, simply because patients generally have the right to make these decisions, may constitute a mockery of the principles that underlie the concept of informed consent. Patients who are decisionally incapable need to be protected from harmful choices (33,118).

Assessment of Decisionmaking Capacity by Courts

On rare occasions, courts are presented with the question of whether or not a patient is competent to refuse treatment. Usually in the course of seeking a judicial determination, the petitioner is also asking the court to appoint a legal guardian to make the decision for the patient, presumably in favor of accepting the proposed treatment. The petitioner may also be asking the court to decide whether the proposed treatment should be provided.

In most cases where judicial determination of decisionmaking capacity is sought, the court relies strongly on the opinions of the patient's physician, other health care providers, the consulting psychiatrist (if there is one), the family, and occasionally the patient.

As mentioned above, a judicial determination of decisionmaking capacity does not necessarily equate to a formal decision of the patient's legal status as a competent adult. An individual may be considered legally competent, and therefore retain all of the attendant rights (e.g., the right to vote, make a contract, or write a will), but still be declared incapable of making the specific decision in question. Conversely, a court may declare the individual incompetent and appoint a guardian to manage *all* aspects of his or her life, even though only one type of ability was originally in question.

Recourse to a court to determine a patient's decisionmaking capacity is not routine, and many commentators do not believe it should be (7,77,78,91). Health care providers and families tend to avoid seeking court resolution on questions of decisionmaking capacity because such determinations can be costly, time-consuming, and emotionally stressful. Judicial hearings are generally open to the public and may lead to publicity that disturbs those who prefer private resolution of such matters. Moreover, although it is possible in an emergency to get a quick judicial resolution, in the ordinary situation, the wheels of justice grind very slowly. State court systems are usually backlogged, and patients with life-threatening conditions often die before their cases are decided (although some cases have been decided after the patient died).

There is no evidence that judges have a better analytic ability or ethical framework on which to determine decisionmaking capacity than those who work in health care institutions. Although they may be less biased than those who care for the patient, judges have little experience with these types of cases and, by and large, rest their decisions on the caregivers' recommendations. Thus, little may be gained by bringing these determinations to court. Moreover, there is a small risk that once the assessment of decisionmaking capacity is brought to court, a judge may rule on the patient's legal status as a competent adult. The patient might not only be disempowered in the context of the specific health care decision, but could lose all the fundamental rights that accompany the legal presumption of competence (118).

The foregoing discussion is not meant to imply that it is never appropriate to ask courts to rule upon a patient's decisionmaking capacity. Courts are the appropriate forums for the determination and protection of individual rights, and some legal experts argue that a court hearing is the most appropriate procedure for determining decisionmaking capacity (11). Others believe that a court hearing is appropriate only in certain cases, for example, when health care providers disagree among themselves or disagree with family members about whether a patient is decisionally capable. Alternatively, there may be patients whose decisionmaking capacity is so questionable that caregivers require a judicial declaration before they are comfortable in accepting the patient's decision. In most cases, however, the question of a patient's decisionmaking capacity, can be decided in the health care institution, *if* caregivers are sensitive to factors that may affect either the patient's capacity or the assessment, including institutional setting and caregiver biases (118). In some institutions, this is a big *if*.

Substantive Criteria for Determining Decisionmaking Capacity

There are few published judicial pronouncements on the substantive criteria for assessing decisionmaking capacity. This situation is primarily attributable to three factors. First, as previously noted, judicial determination of decisionmaking capacity in the context of health care decisions is rare, and courts have therefore had few opportunities to consider the issue. Second, the courts that have ruled in cases involving capacity and medical decisionmaking have, for the most part, been presented with patients who were clearly decisionally incapable. In those cases, the judicial opinion focused not on the ability of the patient to make the decision, but rather on the authority of a third party to make decisions on the patient's behalf. Third, the courts that hear these cases frequently do not issue written opinions.

Legal scholars have identified three approaches to determining decisionmaking capacity: outcome, status, and functional ability. Under the outcome approach, the determination of decisionmaking capacity is based on whether the patient's actual decisions reflect community values and conventional wisdom about appropriate health care. Under the status approach, an individual's decisionmaking capacity is determined on the basis of his or her status in predetermined categories (i.e., consciousness, age, physical or mental diagnosis) without regard to his or her actual decisionmaking capacity. The functional approach focuses on the individual's actual functioning in decisionmaking situations (5,90).

The few courts that have considered criteria for determining decisionmaking capacity have generally adopted the functional approach rather than the outcome or status approach. Commentators have proposed four possible tests to measure a person's decisionmaking capacity using the functional approach:

1. evidencing a choice,
2. evidencing an understanding of relevant information and issues,
3. rationally manipulating the relevant information, and
4. in addition to the above three, appreciating the nature of the situation (7).

Appreciating the nature of the situation is seen as "distinct from factual understanding in that it requires the subject to consider the relevance to his immediate situation of those facts he has understood previously in the abstract" (98). It is regarded as the strictest test.

Two cases illustrate the functional approach to determining decisionmaking capacity. Both cases involved elderly patients who refused life-saving amputation of gangrenous limbs. Applying similar criteria, the courts judged one patient decisionally capable and the other decisionally incapable.

A 1978 Massachusetts case, *Lane* v. *Candura* (68), concerned a 77-year-old widow who initially vacillated and ultimately refused to allow amputation of her gangrenous leg. In the court's opinion, Mrs. Candura possessed "the legally requisite competence of mind and will to make the choice for herself." The court recognized that the patient was "lucid on some matters and confused on others." The focus of the court's inquiry, however, was on whether she made a choice "with full appreciation of the consequences." With that perspective, the court found Candura to be capable of making her "most unfortunate" but "not . . . uninformed decision" (68). The court stated:

> Senile symptoms, in the abstract, may, of course, justify a finding of incompetence, but the inquiry must be more particular. What is lacking in this case is evidence that Mrs. Candura's areas of forgetfulness and confusion cause, or relate in any way to, impairment of her ability to understand that in rejecting the amputation she is, in effect, choosing death over life (68).

The *Candura* court cited for support a 1973 Pennsylvania case, *In re Yetter* (57), and a 1978 New Jersey case, *In re Quackenbush* (51), in which patients with fluctuating lucidity were declared capable of refusing life-sustaining surgery. For the *Candura* court, the key factor in determining decisional capacity was the patient's capability of "appreciating the nature and consequences" of refusing treatment (68).

This focus on the patient's ability to appreciate and understand the nature and consequences of refusing treatment was also important to the court in a 1978 Tennessee case, *State Department of Human Services* v. *Northern* (107). Mary Northern was a 72-year-old patient with gangrenous feet who refused permission for her feet to be amputated. She was considered to be generally lucid and of sound mind. On the one issue of her rotting feet, however, Northern would not recognize the seriousness of her condition or the possibility that she might die without surgery. In fact, the court stated, "she evinces a strong desire to live and an equally strong desire to keep her dead feet" (107).

For the *Northern* court, it was the woman's inability publicly to give evidence of "a comprehension of the facts of her condition" that led the court to hold Northern incapable of making the decision (107). The court stated:

> Capacity means mental ability to make a rational decision, which includes the ability to perceive, appreciate all relevant facts . . . . On the subjects of death and amputation of her feet, her comprehension is blocked, blinded, or dimmed to the extent she is incapable of recognizing facts which would be obvious to a person of normal perception (107).

Thus, the courts in both of these cases chose to emphasize the patient's ability to comprehend and appreciate both the situation and the consequences of refusal of treatment in determining whether the patient has the requisite capacity to refuse treatment.

A variety of tests to determine a patient's decisionmaking capacity have been proposed (see, for example, President's Commission, 1982 [90]; Roth, et al., 1977 [98]; Stanley, 1983 [106]). There is general agreement that the goal is to construct a test that balances patient autonomy or self-determination and the need to protect decisionally incapable patients from harmful decisions. All the proposed tests measure the patient's capacity to make the particular health care decision at issue, not his or her decisionmaking capacity in general. Yet the tests differ in their language and stringency. Some commentators argue that standards of decisionmaking capacity should change depending on aspects of the specific decision, e.g., the potential risk to the patient and the certainty of treatment outcome (see, for example, Drane, 1985 [33]). The existence of this variety of tests highlights the fact that determinations of decisionmaking capacity reflect conflicting societal judgments about when patients should be accorded the freedom to decide as they please, and when protection, more than autonomy, is the primary goal (118).

LEGAL ASPECTS OF MEDICAL DECISIONMAKING FOR DECISIONALLY CAPABLE ELDERLY PATIENTS

Elderly people who are clearly capable of making decisions, or who have been assessed to be capable by whatever criteria, have the same rights to make health care decisions as do all other adults. Their age in no way diminishes the recognition and respect that caregivers owe to decisionally capable patients who face proposed medical intervention. Thus, a decisionally capable elderly patient has the right to be informed of the diagnosis, prognosis, proposed intervention, risks of that intervention, availability of other options and their risks, and consequences of not intervening at all. After receiving this information, he or she is legally empowered to either consent to or refuse the intervention, even if that refusal should lead to serious harm or death for the patient.

Several State and Federal courts have affirmed the right of decisionally capable elderly patients to refuse unwanted medical interventions whether such refusal involves withholding or withdrawing the treatment. For example, in the 1980 Florida case *Satz* v. *Perlmutter* (100), the appeals court affirmed a trial court order that permitted a 73-year-old, mentally alert, terminally ill, hospitalized patient to be removed from the mechanical ventilator that sustained his breathing. The court stated:

> We find, and agree with, several cases upholding the right of a competent adult patient to refuse treatment for himself. From this agreement, we reach our conclusion that, because Abe Perlmutter has a right to refuse treatment in the first instance, he has a concomitant right to discontinue it (100).

More recently, in a 1984 California case, *Bartling* v. *Superior Court* (13), the appeals court strongly upheld the right of a decisionally capable, elderly patient to discontinue treatment. Mr. Bartling was a 70-year-old man who suffered from five major medical problems, none of which was imminently life-threatening. During a hospitalization for depression, a routine chest X-ray showed a tumor on his lung. Bartling agreed to a biopsy, during the course of which his lung collapsed. Bartling was placed on a mechanical ventilator, and efforts to wean him from it were unsuccessful.

When both Bartling and his wife requested that the ventilator be removed, his physicians refused to comply, and Bartling was placed in "soft restraints" to prevent him from disconnecting the ventilator tubes. Bartling petitioned the court for damages and for an order to restrain the hospital from administering any medical care without his consent. The hospital, a religiously affiliated institution, argued that it was devoted to the preservation of life and that it would be unethical for hospital physicians "to disconnect life-support systems from patients whom they viewed as having the potential for cognitive, sapient life" (13).

The California Court of Appeal found that Bartling was mentally capable of deciding to have the ventilator disconnected and that he "knew he would die if the ventilator were disconnected but nevertheless preferred death to life sustained by mechanical means" (13). In a clear statement of the right of decisionally capable hospitalized patients, the court stated further:

> If the right of the patient to self-determination as to his own medical treatment is to have any meaning at all, it must be paramount to the interests of the patient's hospital and doctors. The right of a competent adult patient to refuse medical treatment is a constitutionally guaranteed right which must not be abridged (13).

Nursing home residents who are decisionally capable have a legal right to be informed and to consent to or refuse any medical intervention, regardless of their age or residence in a nursing home. There is one known (but unpublished) judicial opinion that discusses the right of an elderly, decisionally capable nursing home resident to refuse treatment. In this 1984 case, *In the Matter of Application of Plaza Health and Rehabilitation Center* (58), a New York court found that the resident, an 85-year-old man, was decisionally capable at the time he began refusing to eat ("he knowingly and willingly made that decision with the full understanding of the consequences, a hastened death") and that the facility, therefore, was neither required nor permitted to surgically force-feed him. The judge stated, "I will not, against his wishes, in effect order this 85- or 86-year-old person to be operated upon and/or to be force-fed in any manner, or to be restrained for the rest of his natural life" (58). Although the judge did not explicitly state on what basis he made this decision, it is clear that this opinion is supported by the resident's common law right of self-determination (118).

OTA is not aware of any judicial decisions that explicitly discuss the rights of the decisionally capable, elderly patient at home. However, a 1986 New Jersey case, *In re Farrell* (48) concerned a 37-year-old woman with amyotrophic lateral sclerosis (ALS) who was on a mechanical ventilator at home. The Supreme Court of New Jersey found that the woman was decisionally capable and that the ventilator could be removed as she requested. Observers point out that there is no reason to doubt that an elderly patient's right to make informed, voluntary decisions applies when the patient is living at home, just as it does when the patient is in other settings, and that this right could be judicially vindicated if necessary (32,118).

Despite the legal right of decisionally capable elderly patients to make health care decisions and to refuse unwanted treatment, many practical difficulties can interfere with their exercise of this right, as discussed earlier. Especially troublesome is the possibility that some elderly persons who are decisionally capable and who refuse treatment may be assumed to be or said to be decisionally incapable without a careful and unbiased determination of their decisionmaking capacity. It is not known how often such situations occur, but three factors suggest that they may occur more often than is generally recognized: 1) lack of agreed upon procedures and criteria for determining decisionmaking capacity; 2) the fact that determinations of decisionmaking capacity are sometimes made quickly and informally by health care providers who are barely aware that they are making such a determination (73); and 3) the widespread societal myth that elderly people are generally senile and confused (22).

LEGAL ASPECTS OF MEDICAL DECISIONMAKING FOR DECISIONALLY INCAPABLE ELDERLY PATIENTS

For patients who are clearly incapable of making decisions in general, or who have been assessed to be incapable of making a particular decision, several questions arise:

- Can life-sustaining treatment ever be refused on behalf of a decisionally incapable patient?
- If so, who is empowered to make that decision?
- What criteria should guide a person who is making a decision on behalf of such a patient?

Courts that have considered treatment decisions for persons who are decisionally incapable have begun with the premise that such persons' rights are the same as the rights of persons who are decisionally capable. For example, the court in the 1977 Massachusetts case *Superintendent of Belchertown State School* v. *Saikewicz* (109), which involved possible chemotherapy for a 68-year-old congenitally retarded man, explicitly stated:

> The substantive rights of the competent and the incompetent person are the same in regard to the right to decline potentially life-prolonging treatment . . . . The recognition of that right must extend to the case of an incompetent, as well as a competent, patient because the value of human dignity extends to both (109).

Since courts have recognized the uniform applicability of the fundamental rights of patients in medical decisionmaking, the challenge has been to develop procedures and substantive criteria for decisionmaking that protect these rights and at the same time protect vulnerable patients from harmful decisions and protect societal interests related to the decisions (5). Case law and statutes provide a variety of procedures to accomplish these goals. Among them are procedures for designating a surrogate decisionmaker (as authorized by durable power of attorney, guardianship, and family consent laws and some living will statutes) and procedures for documenting a patient's treatment preferences while the patient is decisionally capable—notably living wills. In addition, several courts have outlined substantive criteria to guide decisionmaking for persons who are decisionally incapable and/or set out procedures for reviewing treatment decisions for such persons. These criteria and procedures vary in different States because of differences in case law and statutes in each State. Thus, no one description covers every jurisdiction.

Criteria and procedures for decisionmaking for persons who are decisionally incapable are extremely important for the technologies and the kinds of patients that are the focus of this report. Although in medical practice in general, most patients are decisionally capable, many patients who are candidates for the five technologies discussed in this report are not decisionally capable at the time treatment decisions must be made. No reliable figures are available on the number of such patients. As discussed in chapters 8 and 9, however, some of the elderly people who are candidates for tube feeding or life-sustaining antibiotic therapy are confused as a result of organic diseases that cause dementia. People with such diseases are sometimes also candidates for resuscitation, mechanical ventilation, and dialysis. Furthermore, many persons who are not demented may be so sick at the time decisions about life-sustaining technologies must be made that they are not able to participate in the decisions. At the extreme are patients who are unconscious at the time of the decision.

Most decisions about life-sustaining treatments for decisionally incapable elderly patients arise in hospitals or nursing homes, but the courts that have considered cases involving such decisions have generally not limited the applicability of their rulings to specific settings. An exception was the 1985 ruling of the New Jersey Supreme Court in the case of Claire Conroy (46), which was held to apply only to nursing home residents (see discussion below).

Designating a Surrogate Decisionmaker

In many jurisdictions, adults are legally authorized to appoint, in advance of incapacity, another person to act as a surrogate or proxy decisionmaker. In the event that the individual subsequently becomes incapable of making health care decisions, the surrogate is empowered to act.

The advance appointment of a surrogate decisionmaker by a patient has several preconditions. The patient must be capable of making decisions at the time the directive is made, must have thought about the need to appoint a surrogate in advance, and must have had someone available and willing to take on that role. For elderly individuals without relatives or close friends, appointing a surrogate may be difficult.

For individuals who have someone to appoint as surrogate, designating this person in advance can minimize confusion and uncertainty in future medical decisions. Selecting a surrogate in advance assures the patient that someone trustworthy and knowledgeable will be acting on his or her behalf if it becomes necessary.

If a patient has not appointed a surrogate before becoming decisionally incapable, health care providers who must make treatment decisions for the patient may turn to the courts to appoint a surrogate. More frequently though, they designate (formally or informally) a family member or friend of the patient to act as the surrogate. Who is designated as a surrogate in either of these situations depends on several factors, including the case law and statutes of the jurisdiction and the availability of family or close friends of the patient.

According to one observer, a surrogate decisionmaker should possess the following qualities:

- he or she should have no conflict of interest or should be able to overcome a potential conflict of interest;
- he or she should have the capacity to participate in the decisionmaking process in an informed and conscientious manner (with the necessary corollary that health care providers must provide the appropriate information); and
- he or she should have the ability to advocate the patient's interests throughout the decisionmaking process (25).

Advance Appointment of a Surrogate Decisionmaker by the Patient

Depending on the State, an individual can appoint a surrogate decisionmaker through either a durable power of attorney or a living will. All States and the District of Columbia have a durable power of attorney statute. These statutes permit individuals (known as "principals") to delegate to another (known as the "proxy," "agent," or "attorney in fact") the legal authority to act on the principal's behalf. Such empowerment is "durable" because, unlike the traditional power of attorney, it does not automatically terminate if the principal subsequently becomes incompetent.

Durable power of attorney statutes were originally intended to permit financial or property transactions in the absence of the principal. Nothing in the language of these statutes precludes or limits the use of a durable power of attorney as a device for delegating medical decisionmaking authority, and no court has ruled that a durable power of attorney cannot be used for this purpose (5). However, some uncertainty remains, except in the 15 States[2] that expressly allow this use (either through statutes or their interpretation) (27,83).

Some States, for example, California and Rhode Island, have a specific form that is used to establish a durable power of attorney for health care. The California form is illustrated in figure 3-1. Most States do not require a specific form, however. A sample form that could be used in any of these States is illustrated in figure 3-2. In some States, a durable power of attorney for health care must be notarized to be valid, and in some States, it must be filed with a specific government office (83).

The process of executing a durable power of attorney may encourage an individual to consider his or her treatment preferences and discuss them

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[2] Arizona, California, Colorado, Connecticut, Hawaii, Idaho, Iowa Maryland, Nevada, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, and Virginia (27).

Figure 3-1.—California's Form for Creating a Durable Power of Attorney for Health Care

CALIFORNIA
STATUTORY FORM DURABLE POWER OF ATTORNEY FOR HEALTH CARE
(California Civil Code Section 2500)

Warning to Person Executing This Document

This is an important legal document which is authorized by the Keene Health Care Agent Act. Before executing this document, you should know these important facts:

This document gives the person you designate as your agent (the attorney in fact) the power to make health care decisions for you. Your agent must act consistently with your desires as stated in this document or otherwise made known.

Except as you otherwise specify in this document, this document gives your agent the power to consent to your doctor not giving treatment or stopping treatment necessary to keep you alive.

Notwithstanding this document, you have the right to make medical and other health care decisions for yourself so long as you can give informed consent with respect to the particular decision. In addition, no treatment may be given to you over your objection at the time, and health care necessary to keep you alive may not be stopped or withheld if you object at the time.

This document gives your agent authority to consent, to refuse to consent, or to withdraw consent to any care, treatment, service, or procedure to maintain, diagnose, or treat a physical or mental condition. This power is subject to any statement of your desires and any limitations that you include in this document. You may state in this document any types of treatment that you do not desire. In addition, a court can take away the power of your agent to make health care decisions for you if your agent (1) authorizes anything that is illegal, (2) acts contrary to your known desires, or (3) where your desires are not known, does anything that is clearly contrary to your best interests.

Unless you specify a shorter period in this document, this power will exist for seven years from the date you execute this document and, if you are unable to make health care decisions for yourself at the time when this seven-year period ends, this power will continue to exist until the time when you become able to make health care decisions for yourself.

You have the right to revoke the authority of your agent by notifying your agent or your treating doctor, hospital, or other health care provider orally or in writing of the revocation.

Your agent has the right to examine your medical records and to consent to their disclosure unless you limit this right in this document.

Unless you otherwise specify in this document, this document gives your agent the power after you die to (1) authorize an autopsy, (2) donate your body or parts thereof for transplant or therapeutic or educational or scientific purposes, and (3) direct the disposition of your remains.

This document revokes any prior durable power of attorney for health care.

You should carefully read and follow the witnessing procedure described at the end of this form. This document will not be valid unless you comply with the witnessing procedure.

If there is anything in this document that you do not understand, you should ask a lawyer to explain it to you.

Your agent may need this document immediately in case of an emergency that requires a decision concerning your health care. Either keep this document where it is immediately available to your agent and alternate agents or give each of them an executed copy of this document. You may also want to give your doctor an executed copy of this document.

Do not use this form if you are a conservatee under the Lanterman-Petris-Short Act and you want to appoint your conservator as your agent. You can do that only if the appointment document includes a certificate of your attorney.

SOURCE: California Civil Code Sections 2410-2443.

Figure 3-1.—California's Form for Creating a Durable Power of Attorney for Health Care—Continued

1. Designation of Health Care Agent.

I, ____

(Insert your name and address)

____

do hereby designate and appoint ____

____

(Insert name, address and telephone number of one individual only as your agent to make health care decisions for you. None of the following may be designated as your agent: (1) your treating health care provider, (2) a nonrelative employee of your treating health care provider, (3) an operator of a community care facility, or (4) a nonrelative employee of an operator of a community care facility.)

as my attorney in fact (agent) to make health care decisions for me as authorized in this document. For the purposes of this document, "health care decision" means consent, refusal of consent, or withdrawal of consent to any care, treatment, service, or procedure to maintain, diagnose, or treat an individual's physical or mental condition.

2. Creation of Durable Power of Attorney for Health Care.

By this document I intend to create a durable power of attorney for health care under Sections 2430 to 2443, inclusive, of the California Civil Code. This power of attorney is authorized by the Keene Health Care Agent Act and shall be construed in accordance with the provisions of Sections 2500 to 2506, inclusive, of the California Civil Code. This power of attorney shall not be affected by my subsequent incapacity.

3. General Statement of Authority Granted.

Subject to any limitations in this document, I hereby grant to my agent full power and authority to make health care decisions for me to the same extent that I could make such decisions for myself if I had the capacity to do so. In exercising this authority, my agent shall make health care decisions that are consistent with my desires as stated in this document or otherwise made known to my agent, including, but not limited to, my desires concerning obtaining or refusing or withdrawing life-prolonging care, treatment, services, and procedures.

(If you want to limit the authority of your agent to make health care decisions for you, you can state the limitations in paragraph 4 ["Statement of Desires, Special Provisions, and Limitations"] below. You can indicate your desires by including a statement of your desires in the same paragraph.)

4. Statement of Desires, Special Provisions, and Limitations.

(Your agent must make health care decisions that are consistent with your known desires. You can, but are not required to, state your desires in the space provided below. You should consider whether you want to include a statement of your desires concerning life-prolonging care, treatment, services, and procedures. You can also include a statement of your desires concerning other matters relating to your health care. You can also make your desires known to your agent by discussing your desires with your agent or by some other means. If there are any types of treatment that you do not want to be used, you should state them in the space below. If you want to limit in any other way the authority given your agent by this document, you should state the limits in the space below. If you do not state any limits, your agent will have broad powers to make health care decisions for you, except to the extent that there are limits provided by law.)

In exercising the authority under this durable power of attorney for health care, my agent shall act consistently with my desires as stated below and is subject to the special provisions and limitations stated below:

(a) Statement of desires concerning life-prolonging care, treatment, services, and procedures:

(b) Additional statement of desires, special provisions, and limitations:

(You may attach additional pages if you need more space to complete your statement. If you attach additional pages, you must date and sign EACH of the additional pages at the same time you date and sign this document.)

5. Inspection and Disclosure of Information Relating to My Physical or Mental Health.

Subject to any limitations in this document, my agent has the power and authority to do all of the following:

(a) Request, review, and receive any information, verbal or written, regarding my physical or mental health, including, but not limited to, medical and hospital records.

Figure 3-1.—California's Form for Creating a Durable Power of Attorney for Health Care—Continued

(b) Execute on my behalf any releases or other documents that may be required in order to obtain this information.

(c) Consent to the disclosure of this information.

(If you want to limit the authority of your agent to receive and disclose information relating to your health, you must state the limitations in paragraph 4 ["Statement of Desires, Special Provisions, and Limitations"] above.)

6. Signing Documents, Waivers, and Releases.

Where necessary to implement the health care decisions that my agent is authorized by this document to make, my agent has the power and authority to execute on my behalf all of the following:

(a) Documents titled or purporting to be a "Refusal to Permit Treatment" and "Leaving Hospital Against Medical Advice."

(b) Any necessary waiver or release from liability required by a hospital or physician.

7. Autopsy; Anatomical Gifts; Disposition of Remains.

Subject to any limitations in this document, my agent has the power and authority to do all of the following:

(a) Authorize an autopsy under Section 7113 of the Health and Safety Code.

(b) Make a disposition of a part or parts of my body under the Uniform Anatomical Gift Act (Chapter 3.5 [commencing with Section 7150] of Part 1 of Division 7 of the Health and Safety Code).

(c) Direct the disposition of my remains under Section 7100 of the Health and Safety Code.

(If you want to limit the authority of your agent to consent to an autopsy, make an anatomical gift, or direct the disposition of your remains, you must state the limitations in paragraph 4 ["Statement of Desires, Special Provisions, and Limitations"] above.)

8. Duration.

(Unless you specify a shorter period in the space below, this power of attorney will exist for seven years from the date you execute this document and, if you are unable to make health care decisions for yourself at the time when this seven-year period ends, the power will continue to exist until the time when you become able to make health care decisions for yourself.)

This durable power of attorney for health care expires on:

____

(Fill in this space ONLY if you want the authority of your agent to end EARLIER than the seven-year period described above.)

9. Designation of Alternate Agents.

(You are not required to designate any alternate agents but you may do so. Any alternate agent you designate will be able to make the same health care decisions as the agent you designated in paragraph 1, above, in the event that the agent is unable or ineligible to act as your agent. If the agent you designated is your spouse, he or she becomes ineligible to act as your agent if your marriage is dissolved.)

If the person designated as my agent in paragraph 1 is not available or becomes ineligible to act as my agent to make a health care decision for me or loses the mental capacity to make health care decisions for me, or if I revoke that person's appointment or authority to act as my agent to make health care decisions for me, then I designate and appoint the following persons to serve as my agent to make health care decisions for me as authorized in this document, such persons to serve in the order listed below:

A. First Alternate Agent ________________________________

____

(Insert name, address, and telephone number of first alternate agent)

B. Second Alternate Agent ________________________________

____

(Insert name, address, and telephone number of second alternate agent)

10. Nomination of Conservator of Person.

(A conservator of the person may be appointed for you if a court decides that one should be appointed. The conservator is responsible for your physical care, which under some circumstances includes making health care decisions for you. You are not required to nominate a conservator but you may do so. The court will appoint the person you nominate unless that would be contrary to your best interests. You may, but are not required to, nominate as your conservator the same person you named in paragraph 1 as your health care agent. You can nominate an individual as your conservator by completing the space below.)

If a conservator of the person is to be appointed for me, I nominate the following individual to serve as conservator of the person:

____

(Insert name and address of person nominated as conservator of the person)

____

11. Prior Designations Revoked.

I revoke any prior durable power of attorney for health care.

Figure 3-1.—California's Form for Creating a Durable Power of Attorney for Health Care—Continued

Date and Signature of Principal

(YOU MUST DATE AND SIGN THIS POWER OF ATTORNEY)

I sign my name to this Statutory Form Durable Power of Attorney for Health Care on

_______________ at _______________ , _______________
(Date) (City) (State)

____
(You sign here)

(This power of attorney will not be valid unless it is signed by two qualified witnesses who are present when you sign or acknowledge your signature. If you have attached any additional pages to this form, you must date and sign each of the additional pages at the same time you date and sign this power of attorney.)

Statement of Witnesses

(This document must be witnessed by two qualified adult witnesses. None of the following may be used as a witness: (1) a person you designate as your agent or alternate agent, (2) a health care provider, (3) an employee of a health care provider, (4) the operator of a community care facility, (5) an employee of an operator of a community care facility. At least one of the witnesses must make the additional declaration set out following the place where the witnesses sign.)

(READ CAREFULLY BEFORE SIGNING. You can sign as a witness only if you personally know the principal or the identity of the principal is proved to you by convincing evidence.)

(To have convincing evidence of the identity of the principal, you must be presented with and reasonably rely on any one or more of the following:

(1) An identification card or driver's license issued by the California Department of Motor Vehicles that is current or has been issued within five years.

(2) A passport issued by the Department of State of the United States that is current or has been issued within five years.

(3) Any of the following documents if the document is current or has been issued within five years and contains a photograph and description of the person named on it, is signed by the person, and bears a serial or other identifying number:

(a) A passport issued by a foreign government that has been stamped by the United States Immigration and Naturalization Service.
(b) A driver's license issued by a state other than California or by a Canadian or Mexican public agency authorized to issue drivers' licenses.
(c) An identification card issued by a state other than California.
(d) An identification card issued by any branch of the armed forces of the United States.)
(Other kinds of proof of identity are not allowed.)

I declare under penalty of perjury under the laws of California that the person who signed or acknowledged this document is personally known to me (or proved to me on the basis of convincing evidence) to be the principal, that the principal signed or acknowledged this durable power of attorney in my presence, that the principal appears to be of sound mind and under no duress, fraud, or undue influence, that I am not the person appointed as attorney in fact by this document, and that I am not a health care provider, an employee of a health care provider, the operator of a community care facility, nor an employee of an operator of a community care facility.

_______________ (Signature—Witness 1)	_______________ (Signature—Witness 2)
_______________ (Print Name)	_______________ (Print Name)
_______________ (Residence Address) _______________	_______________ (Residence Address) _______________
_______________ (Date)	_______________ (Date)

(AT LEAST ONE OF THE ABOVE WITNESSES MUST ALSO SIGN THE FOLLOWING DECLARATION.)

I further declare under penalty of perjury under the laws of California, that I am not related to the principal by blood, marriage, or adoption, and, to the best of my knowledge, I am not entitled to any part of the estate of the principal upon the death of the principal under a will now existing or by operation of law.

Signature: _______________ Signature: _______________

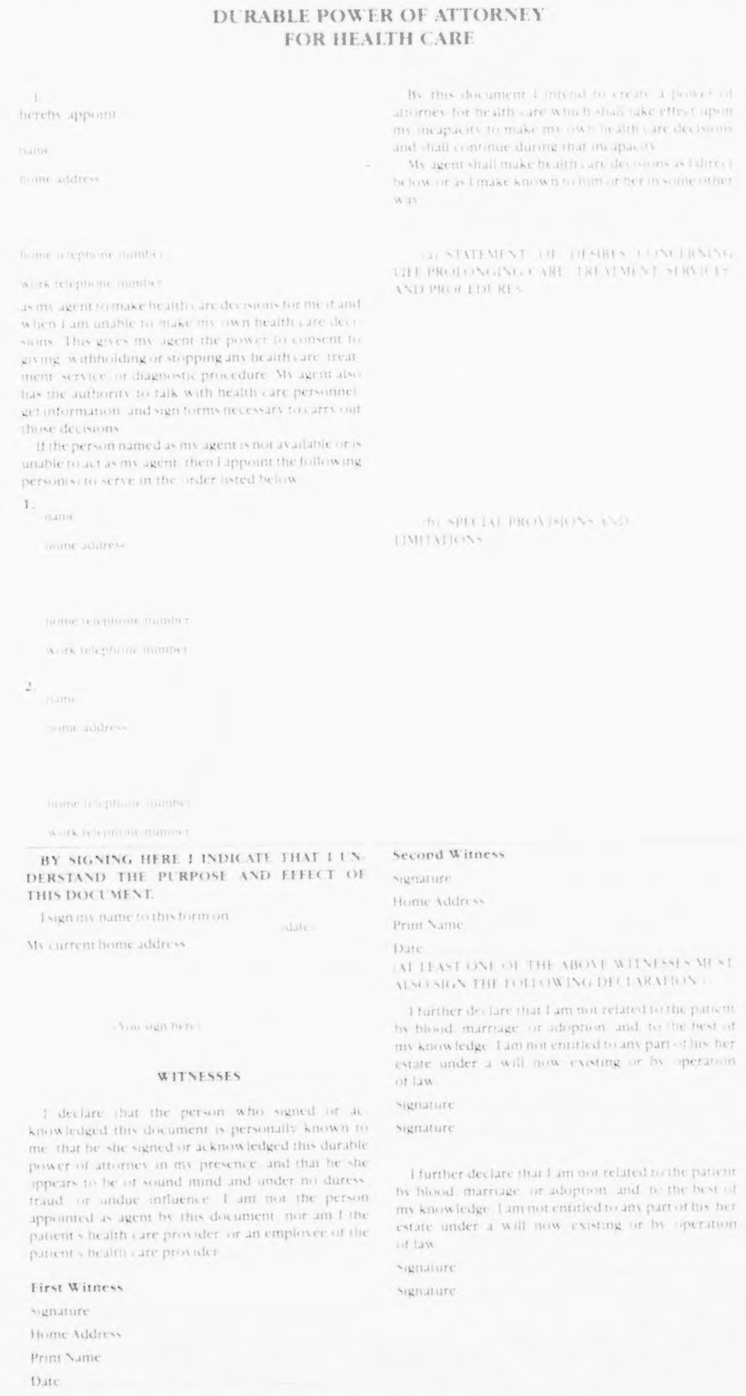
Statement of Patient Advocate or Ombudsman

(If you are a patient in a skilled nursing facility, one of the witnesses must be a patient advocate or ombudsman. The following statement is required only if you are a patient in a skilled nursing facility—a health care facility that provides the following basic services: skilled nursing care and supportive care to patients whose primary need is for availability of skilled nursing care on an extended basis. The patient advocate or ombudsman must sign both parts of the "Statement of Witnesses" above AND must also sign the following statement.)

I further declare under penalty of perjury under the laws of California that I am a patient advocate or ombudsman as designated by the State Department of Aging and that I am serving as a witness as required by subdivision (f) of Section 2432 of the Civil Code.

Signature: _______________

Figure 3-2.—Sample of a General Form for Creating a Durable Power of Attorney for Health Care



DURABLE POWER OF ATTORNEY
FOR HEALTH CARE

I,
hereby appoint:

name

home address

home telephone number

work telephone number

as my agent to make health care decisions for me if and when I am unable to make my own health care decisions. This gives my agent the power to consent to giving, withholding or stopping any health care, treatment, service, or diagnostic procedure. My agent also has the authority to talk with health care personnel, get information, and sign forms necessary to carry out those decisions.

If the person named as my agent is not available or is unable to act as my agent, then I appoint the following person(s) to serve in the order listed below:

1.
name

home address

home telephone number

work telephone number

2.
name

home address

home telephone number

work telephone number

By this document I intend to create a power of attorney for health care which shall take effect upon my incapacity to make my own health care decisions and shall continue during that incapacity.

My agent shall make health care decisions as I direct below or as I make known to him or her in some other way.

(a) STATEMENT OF DESIRES CONCERNING LIFE-PROLONGING CARE, TREATMENT, SERVICES, AND PROCEDURES:

(b) SPECIAL PROVISIONS AND LIMITATIONS:

BY SIGNING HERE I INDICATE THAT I UNDERSTAND THE PURPOSE AND EFFECT OF THIS DOCUMENT.

I sign my name to this form on
(date)

My current home address:

(You sign here)

WITNESSES

I declare that the person who signed or acknowledged this document is personally known to me, that he/she signed or acknowledged this durable power of attorney in my presence, and that he/she appears to be of sound mind and under no duress, fraud, or undue influence. I am not the person appointed as agent by this document, nor am I the patient's health care provider, or an employee of the patient's health care provider.

First Witness

Signature:

Home Address:

Print Name:

Date:

Second Witness

Signature:

Home Address:

Print Name:

Date:

(AT LEAST ONE OF THE ABOVE WITNESSES MUST ALSO SIGN THE FOLLOWING DECLARATION.)

I further declare that I am not related to the patient by blood, marriage, or adoption, and, to the best of my knowledge, I am not entitled to any part of his/her estate under a will now existing or by operation of law.

Signature:

Signature:

I further declare that I am not related to the patient by blood, marriage, or adoption, and, to the best of my knowledge, I am not entitled to any part of his/her estate under a will now existing or by operation of law.

Signature:

Signature:

SOURCE: Barbara Mishkin, Hogan & Hartson, Washington, DC.

with the surrogate so that when decisions must be made, they will reflect what the individual would have chosen (118). Anecdotal evidence suggests, however, that some individuals who execute durable powers of attorney do not discuss their treatment preferences with the designated surrogate. Some do not even notify the person they have designated as their surrogate that the durable power of attorney has been executed. In such situations, the designated surrogate may be ill-prepared to make treatment decisions on the principal's behalf (35).

In seven States,[3] statutes that authorize living wills allow individuals to appoint a surrogate decisionmaker through their living will (27). (Living wills—documents in which an individual sets forth his or her wishes concerning life-sustaining treatments in the event that he or she becomes decisionally incapable—are discussed at greater length later in this chapter.) Depending on the State statute, a surrogate appointed through a living will can perform any of several functions: serving as an advocate for the patient's preferences as explicitly documented in the living will, filling in gaps or clearing up confusion about the patient's explicit directives based on prior discussions with the patient, or making decisions when the patient has left no explicit directives.

Two States—Indiana and Iowa—do not directly address surrogate appointments in their living will statutes, but by providing for consultation between the physician and the patient's representative, do inferentially authorize such appointments. Moreover, in States that do not require a specific form for a living will, an individual may be able to include a surrogate appointment. The legal authority of surrogates appointed in this way is uncertain, however (27).

Court-Appointed Surrogate Decisionmaker

Under their *parens patriae* powers, States have the authority and obligation to protect individuals who are incapable of protecting their own interests. This power, derived from English common law, gives courts the authority to appoint legal guardians, both for children (who are categorically considered unable to protect themselves) and for adults who are decisionally incapable. Some States require that the adult first be adjudicated incompetent before a guardian will be appointed; other States recognize that adults can be incapacitated in only certain spheres and will therefore appoint guardians for limited purposes. Appointment proceedings are alternatively known as guardianship, conservatorship, or committeeship proceedings, depending on the State (118).

Resort to a court of law for the appointment of a legal guardian to make health care decisions on behalf of a decisionally incapable adult is not common. It is most likely to occur when the decisionally incapable adult has no family or close friends; or the treatment plan is considered controversial, and health care providers and family want prior judicial guidance and assurance about the appropriateness of their actions; or the health care providers and family or close friends disagree about the course of action to be taken on behalf of the patient. Although courts are willing to appoint legal guardians for the specific purpose of making health care decisions and some of the most noteworthy court decisions about the rights of decisionally incapable patients have arisen in this context (including *In re Quinlan* [52]), a guardianship proceeding can be expensive, time-consuming, and emotionally stressful for the family and for the patient, if he or she is aware of it (83).

Many State guardianship statutes specify a preference for appointing a family member to be the legal guardian. Some States allow people to nominate, while they are decisionally capable, a person to be their court-appointed guardian in the event that they become decisionally incapable in the future and guardianship is required (27).

In some States, it is unclear whether guardians already appointed for general management tasks also have the authority to make health care decisions for their wards. Some States require such a guardian to return to court and seek specific judicial authorization to make health care decisions (118). Under a new law that takes effect in the District of Columbia in July 1987, court-appointed guardians are not allowed to make decisions about life-sustaining treatment for their wards without explicit approval of the court, unless the authority to make such decisions is specifically granted to the guardian when the guardianship is set up (76).

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[3] Delaware, Florida, Louisiana, Virginia, Utah, Texas, and Wyoming (27).

It is often very difficult to find someone to serve as a guardian for persons who do not have a family member or friend to act in this capacity and whose estate is not large enough to pay a lawyer or other individual to act as their guardian. Some States have a public office that serves as the guardian of last resort for such persons. In Arizona, for example, the Public Fiduciary's Office in each county acts as guardian for persons who are adjudicated incompetent and have no other legal guardian. This office is staffed with both lawyers and social workers and is legally empowered to make both financial and treatment decisions for its wards. According to a former public guardian for the State of Arizona, it costs about $500 to establish guardianship through this program and $300 to $500 per year to manage each case (16).

Although the experience with public guardianship has been favorable in Arizona, some public guardianship programs have had problems. In Los Angeles, for example, the public guardian was sued for inappropriate institutionalization of wards, and in other jurisdictions, public guardians have mishandled the funds of wards (102).

Informal Designation of a Surrogate Decisionmaker and Family Consent Laws

In everyday medical practice, few patients who are decisionally incapable have a court-appointed guardian or a surrogate whom they explicitly appointed before they became decisionally incapable. The usual procedure in hospitals, nursing homes, and other health care facilities is for health care providers to turn to the patient's next of kin or other close family or friends who know the patient and seem to have his or her best interests in mind. Frequently, one family member indicates to the provider that he or she will act as the family spokesperson. At other times, the provider informally selects one family member to assist with decisionmaking.

Although this practice frequently works well, it is potentially fraught with difficulty if individual family members disagree about who should be the surrogate decisionmaker or about whether a specific treatment should be provided. In such situations, the health care provider or facility may petition a court or urge the family to petition a court for appointment of a legal guardian. More often, the provider may seek to reconcile the wishes of different family members informally, without insisting that one individual be designated as the surrogate. Anecdotal evidence suggests that the latter approach often leads providers to defensive decisionmaking—that is, the provider may opt for treatment decisions that he or she believes are least likely to result in a successful law suit if one family member chooses to sue.

Fifteen States have family consent laws that empower relatives of decisionally incapable patients to make legally binding decisions on behalf of those patients without a formal guardianship proceeding.[4] In some of these States, family members may make such decisions only after a physician has certified that the patient is terminally ill. Case law in five States[5] supports the right of family members to make health care decisions for patients who are terminally ill or irreversibly comatose (83). In most States, however, there is no legal authority for family members to make decisions on behalf of their elderly relatives even though this is a common and widely accepted practice.

The assumptions that underlie the tradition of informally designated family surrogates include the belief that the family is the most concerned about the patient's best interests, and the belief that the family is the most knowledgeable about the patient's values and preferences. In some cases, this is clearly not true. If there is evidence to contradict either of these beliefs, some commentators advise health care providers to seek legal counsel, and perhaps to petition a court for appointment of a legal guardian (118).

The Substantive Basis for the Surrogate Decision

Ideally, two fundamental values—patient well-being and patient self-determination—should underlie surrogate decisions for persons who are decisionally incapable (90,118). Various courts and legal scholars have developed standards for decisionmaking that reflect these values in differing degrees.

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[4] Arkansas, Florida, Georgia, Idaho, Iowa, Louisiana, Maine, Maryland, Mississippi, New Mexico, North Carolina, Oregon, Texas, Virginia, and Utah (33).

[5] California, Connecticut, Florida, Georgia, and New Jersey (83).

Best Interest v. Substituted Judgment

The two legal standards that generally guide surrogate decisionmaking are the "best interest standard" and the "substituted judgment standard." Each standard guides decisionmaking from a different perspective.

If a patient has left no directives, has failed to convey his or her treatment preferences to anyone, or was never capable of making such decisions, the surrogate must rely on the best interest standard. This standard focuses on objective, societally shared criteria. The surrogate makes the decision from the point of view of a hypothetical "reasonable person" and considers such factors as the relief of suffering, the usefulness or futility of the proposed intervention, and the risks, benefits, and burdens of the proposed intervention to the patient. Most scholars agree that benefits and burdens to family and society should be irrelevant to a decision based on the best interest standard even though such considerations might be a factor in a decisionally capable patient's choice (118).

The substituted judgment standard requires the surrogate to use the patient's personal values and preferences as the basis for health care decisions. Under this standard, the surrogate's decision should be the same decision that the patient would make if he or she were able to decide. As the *Saikewicz* court stated in 1977, this standard requires the surrogate to "don the mental mantle of the incompetent" (109).

The substituted judgment standard is a subjective standard that necessitates that the patient at one time must have been decisionally capable and must have expressed, in some manner, values and preferences that are relevant to the decision to be made. It is generally preferred over the best interest standard when these criteria are met, because it allows the patient's own definition of "well-being" to be in control; also, in a certain way, the substituted judgment standard permits a decisionally incapable patient to exercise his or her right to self-determination, although he or she is unable to do so directly (5,91).

Types of Substituted Judgment Cases

There are two types of substituted judgment cases: those in which the patient explicitly stated wishes and preferences prior to becoming incapable, and those in which the patient made no explicit statement, but where the surrogate is able to infer what the patient would have wanted regarding the specific decision because of a close familiarity with the patient, patient's lifestyle, and patient's patterns of behavior. Some States, such as New York, require an explicit statement supported by "clear and convincing" evidence (55); no inferences are permitted in those jurisdictions. Other States, such as Massachusetts, clearly permit inferences, and even extend the use of what they consider the "substituted judgment" standard to situations where the patient was *never* capable of judgment in the first place. In either case, the most effective way for individuals to ensure that decisions about their treatment will reflect their own values and preferences, should they someday be incapable of making decisions for themselves, is through the use of an advance directive (i.e., a durable power of attorney, a living will, or both) (118).

An example of a substituted judgment case involving an explicit prior statement is that of Brother Fox, an 83-year-old member of the Roman Catholic Society of Mary, who, following routine hernia surgery, was left in a permanent vegetative state on a mechanical ventilator. During a prior bioethical discussion of the Karen Ann Quinlan case, Brother Fox had expressed to his fellow clerics a personal desire not to be maintained by "extraordinary means" if he were ever in a similar situation. As the court noted, the issue of whether or not someone else can speak for the patient "is not presented in this case because here Brother Fox made the decision for himself before he became incompetent" (55). Since Brother Fox's prior statements of desires were "obviously solemn pronouncements," the court ruled that they must be followed. As the New York court noted, prior declarations can provide "clear and convincing" evidence of a person's wishes, and in the absence of evidence to the contrary should be considered the best evidence of the declarant's actual preferences (55).

An example of substituted judgment by inference when no explicit prior statement exists is the 1983 Washington State case *In re Colyer* (45). The patient was a 69-year-old woman who had sustained a cardiac arrest. Although she was resuscitated by paramedics, Bertha Colyer suffered massive brain damage. She was placed on a mechanical ventilator and remained in a comatose, unresponsive state. The Washington court said that "her prognosis for any sort of meaningful existence was zero" (45). Colyer's husband, who was her legal guardian, asked the court for permission to remove the ventilator. Although the patient had never explicitly stated her preferences regarding such an act, her husband inferred that this would have been her decision, had she been able to decide. The *Colyer* court commented:

> There is no evidence that Bertha Colyer explicitly expressed her desire to refuse life-sustaining treatment. Nevertheless, her husband and her sisters agreed that Bertha Colyer was a very independent woman, that she disliked going to doctors, and, if able to express her views, that she would have requested the treatment be withdrawn. Given the unanimity of the opinions expressed by Bertha's closest kin, together with the absence of any ill motives, we were satisfied that Bertha's guardian was exercising his best judgment as to Bertha's personal choice when he requested the removal of the life support system (45).

In the 1985 New Jersey case *In re Conroy* (46), the court discussed various ways a surrogate might make a substituted judgment despite the lack of a prior explicit statement. Just as the *Colyer* court noted such factors as the patient's prior independence, her dislike of doctors, and her family's unanimity about what she would have wanted, so too did the Conroy court outline relevant information. The *Conroy* court stated:

> . . . an intent not to have life-sustaining medical intervention . . . might take the form of reactions the patient voiced regarding medical treatment administered to others . . . It might also be deduced from a person's religious beliefs and the tenets of that religion . . . or from the patient's consistent pattern of conduct with respect to prior decisions about his own medical care (46).

The *Conroy* court, however, recognized that while all relevant evidence should be considered "the probative value of such evidence may vary depending on the remoteness, consistency, and thoughtfulness of the prior statements or actions and the maturity of the person at the time of the statements or acts" (46).

The *Conroy* court set forth three alternate standards for surrogate decisionmaking that depend on the amount of evidence that is available about the patient's preferences, and the benefits, burdens, pain, and suffering associated with continued treatment. The three standards are:

1. a *subjective test*, where it is "clear that the particular patient would have refused the treatment under the circumstances involved";
2. a *limited-objective test*, which permits treatment to be withdrawn if there is *some* trustworthy evidence that the patient would have refused, and "the decisionmaker is satisfied that the burdens of the patient's continued life with the treatment outweigh the benefits of that life for the patient"; and
3. a *pure-objective test*, where there is an absence of trustworthy evidence, but the net burdens of the patient's life with the treatment clearly and markedly outweigh the benefits that the patient derives from life. In addition, the "unavoidable, recurring and severe" pain of the patient's life with treatment is such that administering life-sustaining treatment would be "inhumane" (46).

It must be noted, however, that the *Conroy* court restricted its opinion to cases involving "nursing home residents, suffering from serious and permanent mental and physical impairments, who will probably die within 1 year, even with treatment, and who, though formerly competent, are now incompetent to make decisions about their life-sustaining treatment and are unlikely to regain such competence" (46).

Judicial Review of Surrogate Decisions

Whether a court must review a surrogate's decision to withhold or withdraw life-sustaining treatment on behalf of a decisionally incapable patient varies widely among jurisdictions. Even within the same jurisdiction, some types of cases appear to require more review than others, depending on the treatment setting, the treatment options, and the vulnerability of the class to which the patient belongs. In some jurisdictions, cases have been brought to court precisely because of uncertainty about the appropriateness of nonjudicial resolution. In the context of deciding those cases, courts have outlined procedures for surrogates to follow, some of which require judicial involvement.

Two recent Washington State cases, *In re Colyer* (45) and *In re Guardianship of Hamlin* (49), resulted in court decisions that established the following procedures for that State. If the family, the treating physician, and the institutional "prognosis committee" all agree that the patient's prognosis is terminal, then the family may assert the personal right of the incompetent to refuse life-sustaining treatment without seeking prior appointment of a guardian or prior judicial review of the decision. In cases where no family is available, a guardian must be appointed by a court. Once a guardian is appointed, there is no need for judicial involvement in the substantive decision to withhold or withdraw life-sustaining treatment, as long as the guardian, treating physicians, and prognosis committee are all in agreement. In either situation, however, any party is permitted to petition for court intervention, and "if there is a disagreement between parties involved in the decisionmaking process, court intervention would be appropriate" (49).

In the *Quinlan* case (52), the New Jersey court did not expressly address the issue of whether a court-appointed guardian was necessary. The court stated, however, that if the patient's family, guardian, and attending physicians agree that there is no reasonable possibility the patient will emerge from a "comatose condition to a cognitive, sapient state, and that the life-support apparatus should be discontinued," then they should consult with the institution's "ethics committee." If the ethics committee agrees with the prognosis, then treatment may be withdrawn, judicial review is not necessary, and there is no attendant legal liability for any of the involved parties (52).

With regard to nursing home residents, the New Jersey Supreme Court's decision in the *Conroy* case spelled out special procedures, different from those articulated in the *Quinlan* case, because of "the special vulnerability of mentally and physically impaired, elderly persons in nursing homes and the potential for abuse with unsupervised, institutional decisionmaking in such homes" (46). The *Conroy* decision delineated the following procedures:

1. There must be a determination that the patient is incapable of making the particular decision, and a guardian must be named. This is required even if the patient has already been declared legally incompetent and already has a general guardian.
2. If, based on one of the three articulated surrogate standards (see previous *Conroy* discussion), the guardian believes life-sustaining treatment should be withheld or withdrawn, then he must contact the State Ombudsman for Institutionalized People.
3. The Ombudsman must investigate the situation and must receive evidence concerning the patient's condition from the patient's physician and from two physicians unaffiliated with the facility, who must confirm the patient's medical condition and prognosis.
4. If the Ombudsman receives sufficient supportive evidence, and concurs in the decision to withdraw or withhold treatment, then such action is permitted (46).

Thus, although judicial involvement was not required, the involvement and oversight of a State agency was required. Decisions handed down June 24, 1987, by the New Jersey Supreme Court in the cases of Hilda Peters and Nancy Jobes appear to substantially reduce the categories of patients for whom these procedures are required, but they remain in effect for some patients.

A series of cases in Massachusetts set out somewhat confusing and unclear criteria for determining when judicial review of surrogate decisions is necessary. The 1977 Massachusetts case *Superintendent of Belchertown State School* v. *Sai-*

kewicz (109) concerned a 67-year-old, institutionalized, congenitally retarded man who suffered from acute and terminal leukemia. The Massachusetts court explicitly rejected the *Quinlan* procedures and stated that only the court could permit chemotherapy to be withheld from him:

> We take a dim view of any attempt to shift the ultimate decisionmaking responsibility away from the duly established courts of proper jurisdiction to any committee, panel or group, ad hoc or permanent (109).

In the 1978 Massachusetts case *In re Dinnerstein* (47), the patient was a 67-year-old woman with Alzheimer's disease who was in a persistent vegetative state. Her family and physician sought prior judicial approval of a decision not to resuscitate the patient should she suffer a respiratory or cardiac arrest. The court distinguished this case from the *Saikewicz* case, because the latter involved treatment that could prolong life—i.e., treatment that "contemplates, at the very least, a remission of symptoms enabling a return towards a normal, functioning, integrated existence." Since resuscitation does "nothing to cure or relieve the illness which will have brought the patient to the threshhold of death," the court considered a "Do Not Resuscitate" order to be a question for the attending physician, not for a court of law.

Finally, in a 1980 case, *In re Spring* (54), the Massachusetts court attempted to clarify its two earlier opinions. The court articulated a list of factors that might influence the decision about whether prior judicial approval of a surrogate decision is required. The court made no attempt, however, to categorize which combinations of these factors would mandate court review. The factors included the extent of the patient's mental impairments, whether a State institution had custody of the patient, the patient's prognosis with or without the proposed treatment, the risks of treatment, the patient's understanding of these risks, the urgency of the decision, and the clarity of professional opinion as to what would constitute appropriate medical practice in the given situation. The court also noted that while "court approval may serve the useful purpose of resolving a doubtful or disputed question of law or fact, . . . it does not eliminate all risk of liability."

It is thus evident that the necessity for judicial review of surrogate decisions is highly variable, depending on the jurisdiction, the patient's condition, and the setting of the decision. Different jurisdictions place different values on the roles of physicians, families, state agencies, and courts in decisions to withdraw or withhold life-sustaining treatment from decisionally incapable patients. This again reflects the tension that underlies these decisions—a tension between permitting the preferences of previously capable but now decisionally incapable patients to guide surrogate decisionmaking and protecting decisionally incapable patients from harmful decisions.

Living Wills

A living will is a document that gives directions from an individual about how that person wants decisions about life-sustaining treatments to be made in the event that he or she becomes decisionally incapable in the future. When living wills were first devised in 1969, they had no legal sanctioning, but because they enunciated the patient's specific treatment preferences, they were considered morally persuasive (118). Even without specific legal sanctioning, a living will may be considered as a clear expression of the patient's wishes under the substituted judgment standard discussed above (11).

In an attempt to make living wills legally binding and to standardize language, meaning, and usage, many States have enacted legislation establishing formal requirements for living wills. California was the first State to enact such legislation, and the name of its statute, the "Natural Death Act," has become a generic label for living will statutes (118). As of January 1987, 38 States[6] and the District of Columbia had enacted such legislation (104).

Generally, State living will statutes provide immunity from legal liability for health care providers who withhold or withdraw "life-sustaining" or "life-prolonging" treatment from a patient who has a "terminal condition" pursuant to a declaration executed by the patient. Refusal of treatment through a living will is not considered suicide, and health care providers who comply with a patient's living will are protected from prosecution for aiding and abetting suicide, which is a crime in most States (5,111). Apart from these general similarities, however, living will statutes vary significantly from State to State.

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[6] Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Mexico, North Carolina, Oklahoma, Oregon, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming (103).

Variations in State Living Will Statutes

As discussed earlier, living will statutes in seven States specifically allow the appointment of a surrogate decisionmaker, whereas living will statutes in other States do not address this issue. Living will statutes in different States also vary with respect to the form of the declaration, formalities involved in its execution, the nature of the care that can be withheld or withdrawn, and the nature of the patient's condition warranting nontreatment.

Living will statutes in three States require that a particular form must be used without any changes.[7] Most States, however, allow individuals to adapt the basic form to reflect their needs and preferences as long as the State's requirements for a valid living will are followed (83). Utah's living will form (see fig. 3-3) has a specific entry (item 4) that allows an individual to write in any personal instructions that do not contradict the basic intent and requirements of the State act.

All States require that a living will must be signed in the presence of at least two witnesses, but the requirements for who may serve as a witness vary. Because of potential conflicts of interest, living will statutes in some States do not allow relatives, persons who might inherit the individual's estate, or persons who are responsible for the individual's care to act as witnesses (83).

Some States require that living wills be notarized to be valid, and some require that they be filed with a certain State office. In two States, California and Oklahoma, a living will is binding only if the patient signs it *after* he or she is diagnosed as terminally ill (83).

Living wills may be revoked by the individual at any time. In most States, they remain in effect until they are revoked, but in a few States they must be reaffirmed every few years (83).

Living will statutes in most States specify that "life-sustaining" or "life-prolonging" treatments may be withheld or withdrawn in certain circumstances, but that "comfort care" and procedures that are necessary to alleviate pain may not be withheld or withdrawn. Variations in the wording of these provisions in different statutes affect which specific treatments may be withheld or withdrawn. About half the States prohibit withholding or withdrawal of nutritional support and hydration on the basis of a living will (see ch. 8). In addition, the wording of some State living will statutes is unclear with regard to antibiotic therapy (see ch. 9).

Most State living will statutes require that an individual must be "terminally ill" before the living will is implemented, but the definition of "terminally ill" varies in different statutes and is unclear in some. According to one commentator:

> The definition of "terminal illness" (in living will statutes) generally requires diagnosis of an irreversible condition that will lead to death: many States add "with or without the administration of life-sustaining treatment." In many States, death must be "imminent," but imminent is often not defined (83).

The definition of terminal illness in many State living will statutes excludes persons who are in a persistent noncognitive state (or coma) and persons suffering from severe dementia (5,83).

Lack of uniformity among State living will statutes means that living wills that are valid in one State may not be honored in another State. Only four States—Hawaii, Maine, Maryland, and Montana—specifically recognize living wills from other States (83).

The Uniform Rights of the Terminally Ill Act

In 1985, in order to address the lack of uniformity and to correct some perceived anomalies, com-

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[7] California, Idaho, and Oregon (83).

Figure 3-3.—Utah's Form for Creating a Living Will

Directive to Physicians and Providers of Medical Services

This directive is made this ______________ day of ______________, ______________.

1. I, ______________________________, being of sound mind, willfully and voluntarily make known my desire that my life not be artificially prolonged by life-sustaining procedures except as I may otherwise provide in this directive.

2. I declare that if at any time I should have an injury, disease, or illness, which is certified in writing to be a terminal condition by two physicians who have personally examined me, and in the opinion of those physicians the application of life-sustaining procedures would serve only to unnaturally prolong the moment of my death and to unnaturally postpone or prolong the dying process, I direct that these procedures be withheld or withdrawn and my death be permitted to occur naturally.

3. I expressly intend this directive to be a final expression of my legal right to refuse medical or surgical treatment and to accept the consequences from this refusal which shall remain in effect notwithstanding my future inability to give current medical directions to treating physicians and other providers of medical services.

4. I understand that the term "life-sustaining procedure" does not include the administration of medication or sustenance, or the performance of any medical procedure deemed necessary to provide comfort care, or to alleviate pain, except to the extent I specify below that any of these procedures be considered life-sustaining:

5. I reserve the right to give current medical directions to physicians and other providers of medical services so long as I am able, even though these directions may conflict with the above written directive that life-sustaining procedures be withheld or withdrawn.

6. I understand the full import of this directive and declare that I am emotionally and mentally competent to make this directive.

____

Declarant's signature

____

City, County and State of Residence

We witnesses certify that each of us is 18 years of age or older and each personally witnessed the declarant sign or direct the signing of this directive; that we are acquainted with declarant and believe him to be of sound mind; that the declarant's desires are as expressed above; that neither of us is a person who signed the above directive on behalf of the declarant; that we are not related to the declarant by blood or marriage nor are we entitled to any portion of declarant's estate according to the laws of intestate succession of this state or under any will or codicil of declarant; that we are not directly financially responsible for declarant's medical care; and that we are not agents of any health care facility in which the declarant may be a patient at the time of signing this directive.

______________________________	______________________________
Signature of Witness	*Signature of Witness*
______________________________	______________________________
Address of Witness	*Address of Witness*
______________________________	______________________________

SOURCE: Utah Personal Choice and Living Will Act, Utah Code No. 75-2-1101, 1985.

plexities, and impediments in existing State statutes, the National Conference of Commissioners on Uniform State Laws approved a Uniform Rights of the Terminally Ill Act as a model for State legislation (86). The Uniform Act authorizes a person to control decisions about life-sustaining procedures in the event that he or she is in a terminal condition and is unable to participate in treatment decisions. It defines "terminal condition" as "an incurable or irreversible condition that, without the administration of life-sustaining procedures, will, in the opinion of the attending physician, result in death within a relatively short time" (86). "Life-sustaining procedure" is defined as "any medical procedure or intervention that, when administered to a qualified patient, will serve only to prolong the dying process" (86).

The Uniform Act does not rule out withholding or withdrawing any specific medical procedures, including nutritional support and hydration and antibiotics, on the basis of a living will. It does state, however:

> This (act) does not prohibit any action considered necessary by the attending physician for comfort care or alleviating pain (86).

It does not address the appointment of a surrogate decisionmaker.

Reservations About Living Wills

Many different criticisms and reservations about living wills have been expressed. Some commentators are generally opposed to living wills and present many arguments against them. Others generally support the concept of living wills but express reservations about one or more aspects of their interpretation and use or about the requirements of living will statutes in particular States or the Uniform Rights of the Terminally Ill Act.

Because attitudes about withholding and withdrawing life-sustaining procedures vary greatly, some aspects of living wills, State living will statutes, and the Uniform Act that are considered drawbacks by some individuals are considered positive features by others. People who are generally opposed to withholding or withdrawing life-sustaining treatments, for example, approve of provisions in living will legislation that limit their applicability to situations in which death is imminent and provisions that prohibit withholding or withdrawing nutritional support and hydration. Conversely, people who support the patient's right to refuse any unwanted medical interventions usually disapprove of strict limitations on the situations in which they are applicable (i.e., the definition of terminal illness) or limitations on the types of procedures that may be withheld or withdrawn on the basis of a living will.

One frequently mentioned reservation about living wills is that individuals may not be able to accurately predict what their treatment preferences will be at an undetermined time in the future. In this context, some commentators point out that treatment options may change in the future. They also point out that it is difficult for anyone to anticipate all aspects of a future situation that might affect his or her treatment preferences. Thus, some commentators argue that individuals who execute a living will when they are healthy because they believe they will not want life-sustaining treatment if they become terminally ill or severely debilitated may change their minds when actually faced with such a situation (11,67). Supporters of living wills point out that the documents can always be revoked by an oral declaration of the patient. Clearly, a comatose or severely demented patient is not capable of revoking his or her living will. Although some people may regard this as a problem, others do not.

No court has yet considered the case of a decisionally incapable patient who has a valid living will but who gives some indication that he or she wishes to receive treatment that would not otherwise be provided because of the living will. According to one analyst:

> Since one of the primary purposes of executing a living will while competent is to have its provisions carried out should one become incompetent prior to the time it becomes operative, its provisions should arguably be controlling at that time. However, it is difficult to imagine a court ordering life-sustaining treatment to be discontinued in the face of any evidence, however meager, that the patient no longer desires this (111).

Another frequently mentioned reservation about living wills is whether they are specific enough to direct decisionmaking. Some commentators argue that although a living will may indicate a patient's general treatment preferences, it is often too general to provide any meaningful guidance for specific treatment decisions (12,34, 94). For this reason, some people believe that living wills should be regarded as advisory (44). Others believe that living wills are or can be sufficiently specific to direct decisionmaking and that they should be regarded as the patient's decision. In this context, people who oppose living wills argue that they fail to give adequate consideration to the physician's judgment about appropriate medical care for the patient (44).

A third reservation about living wills is that they only allow individuals to refuse treatment they do not want. Some people believe that living wills should also allow individuals to request "maximum care" or specific treatments they do want to receive in the event that they become decisionally incapable (60,67).

Some commentators favor a durable power of attorney over a living will as a method for individuals to ensure that their treatment preferences are recognized if they become decisionally incapable (108). One reason for this is that under a durable power of attorney, the designated surrogate can request treatment, as well as refuse it. In addition, a durable power of attorney is not limited in its applicability to situations in which the patient is terminally ill. Finally, under a durable power of attorney, the designated surrogate can be informed of the details of a specific treatment decision and any newly developed treatment options that the patient could not have been aware of. Thus, a durable power of attorney meets several criticisms of living wills—i.e., that they do not allow individuals to request treatment, that they are limited to situations in which the patient is terminally ill, that they are not specific enough to direct decisionmaking, and that an individual cannot anticipate what treatments may become available in the future.

One concern of some people who support living wills is whether State living will statutes and the Uniform Act include adequate provisions for enforcement. Many State living will statutes and the Uniform Act require health care providers who are unwilling to comply with a patient's living will to transfer the patient to another health care provider who will comply. In some States, the failure of a health care provider to comply with a patient's living will or to transfer the patient to another health care provider who will comply constitutes unprofessional conduct, and in a few States, it is a misdemeanor under State law. In many States, however, failure to comply with a patient's living will or to transfer the patient to another health care provider who will comply carries no penalty (5,83).

The *Bartling* case (13), discussed earlier, illustrates one aspect of the problem of enforcement of a patient's living will. Although Mr. Bartling had executed a valid living will under the California Natural Death Act, it did not become operative because his physicians refused to certify that his condition was terminal within the definition included in the Act (111).

Some commentators argue that the provisions of many State living will statutes and the Uniform Act give physicians too much discretion to determine when and if a patient's living will becomes operative and that they therefore allow physicians to thwart the intentions of patients who have executed valid living wills. Others believe that physician discretion in these matters is necessary and appropriate.

Anecdotal evidence suggests that in some instances, health care providers disregard a patient's living will if one or more members of the patient's family disagree with the patient's directives and ask the physician to treat the patient regardless of his or her advance directive. OTA is not aware of any court cases that have addressed such a situation.

A final, practical problem with living wills is that in some circumstances, health care providers may not be aware that an individual has a living will. This is particularly likely to occur in emergency treatment situations, when the patient's personal physician is not involved in a treatment decision for any reason, and for patients who do not have family or friends to notify the health care provider that the patient has a living will.

The Right To Refuse Treatment Act

Because of dissatisfaction with many provisions of State living will statutes, the Legal Advisors

Committee of Concern for Dying proposed the Right To Refuse Treatment Act (5). This model act would provide a method for individuals who are decisionally capable to appoint a surrogate decisionmaker and specify how they wish to be treated if they become decisionally incapable. It would allow individuals to refuse any medical intervention. Moreover, the act provides that the patient's directives should be followed "even if the continuance of the medical procedure or treatment could prevent or postpone the person's death" (71). Thus, it is not restricted to situations in which the patient is terminally ill. Finally the proposed act provides that failure to comply with a patient's directives shall result in "civil liability and professional disciplinary action, including license revocation or suspension" (71). It has not been enacted in any State but is being considered in 1987 by the Massachusetts legislature.

Future Directions for Living Wills

In spite of the various criticisms and reservations, State living will statutes have provided legitimacy for the idea of advance directives. They outline substance and procedure for patients, surrogates, and physicians to follow, so that these parties can act with some legal guidance and moral comfort, and so that caregivers are more likely to respect the wishes of a previously capable patient. Even the process of debating and enacting such legislation raises public consciousness and encourages more individuals to consider and document their preferences in advance of incapacity (118).

People who strongly oppose withholding and withdrawal of life-sustaining treatment are likely to oppose living wills and living will statutes, regardless of their specific provisions. Other people who support the patient's right to refuse unwanted medical interventions in some or all circumstances may welcome further analysis, debate, and legislative changes that address some of the problems with living wills.

With regard to the question of whether living wills are or can be specific enough to direct decisionmaking, two directions for analysis and debate seem promising. First, advance directives that include both the appointment of a surrogate decisionmaker and explicit documentation of the patient's treatment preferences ideally could result in the surrogate applying and interpreting the patient's preferences in the context of specific treatment situations—including situations the patient did not or could not have specifically anticipated (34,91). Further analysis of the legal and ethical implications and practical difficulties of this approach is needed.

Second, hospitals, nursing homes, and other health care facilities could develop institutional policies to guide physicians and others in the application and interpretation of a patient's living will with respect to a specific proposed intervention. Further analysis of this approach is also needed.

The lack of uniformity of State living will statutes could be addressed through Federal legislation to create a national living will law. Such legislation might include minimum national requirements for executing a valid living will. Because of differences of opinion about living wills, particularly about the nature of the care that can be withheld or withdrawn (i.e., the definition of "life-sustaining treatment") and the nature of the patient's condition warranting nontreatment (i.e., the definition of "terminally ill"), such legislation could face considerable opposition from people who object to the specific definitions used in the proposed legislation. Alternatively, individual States that do not currently recognize a valid living will from another State could be required to revise their living will statute to do so (62). Both approaches require further analysis.

As indicated in the Right To Refuse Treatment Act, one method for enforcing living wills is to legislate specific penalties for a physician or health care facility that fails to honor a patient's living will. Other methods are also possible. At present, the Joint Commission on Accreditation of Hospitals (JCAH) does not require hospitals or nursing homes to have a policy honoring living wills in order to be certified by JCAH. Nor do Medicare and Medicaid require the hospitals and nursing homes that treat Medicare and Medicaid patients to have a policy honoring living wills. In response to a 1986 JCAH survey, about 80 percent of hospitals and nursing homes said that they recognize patients' living wills, and the remaining 20 percent said they do not (74). Changes in the JCAH, Medicare, and Medicaid requirements to require health care facilities to have institutional policies honoring living wills would probably result in acceptance and implementation of patients' living wills in many of the facilities that do not recognize them now.

Further analysis is needed of the proposal that individuals should be allowed to specify in a living will the treatments they do wish to receive if they become decisionally incapable. The legal and ethical implications of this proposal and the practical problems associated with its implementation have received relatively little attention. Especially problematic are the implications of the proposal with respect to the broader legal and ethical question of whether people should have a right to medical care (see ch. 2).

Finally, although the concept of living wills is more widely recognized now than it was a few years ago, most people have not executed a living will. The number who do so may increase in the future, but few observers believe that most patients will ever have a living will. Innovative methods are needed to encourage people who want to document their treatment preferences to execute a living will. This approach leaves unanswered, however, the questions of how to make treatment decisions for patients who did not document their treatment preferences in advance and how to make such decisions for people who were never decisionally capable and thus could not have executed a valid living will.

Nor does it address the question of how persons who are decisionally capable but who live in States that do not have a living will statute can ensure that their treatment preferences will be recognized in the event that they become decisionally incapable. As of January 1987, 12 States[8] did not have a living will statute. Eleven of these States had living will legislation under consideration in 1986, but the bills did not pass (104). In two States that do not have a living will statute—New York and New Jersey—living wills have been recognized by State courts as a clear and convincing statement of a patient's wishes that may be followed by health care providers without specific judicial authorization (83). The validity of a living will in the other 10 States that do not have a living will statute is uncertain.

NONJUDICIAL CONSULTATIVE SOURCES

Several consultative sources are used, to a greater or lesser extent in different facilities and jurisdictions, to facilitate, guide, direct, or monitor decisions about life-sustaining treatments. The legal status of each source with respect to these decisions is unclear, however, except in jurisdictions where specific case law or statutes authorize a role for them in the decisionmaking process.

Institutional Ethics Committees

As noted in chapter 2, institutional ethics committees are multidisciplinary groups established within a hospital or nursing home to address ethical dilemmas that arise within the facility. The percentage of hospitals that have an ethics committee has increased rapidly in the past few years. Now more than 50 percent of hospitals have an ethics committee (29,39). It is not known how many nursing homes have an ethics committee.

Ethics committees may serve any of three different functions in hospitals or nursing homes:

1. Education—Ethics committees often serve as a focal point for multidisciplinary discussion and staff education about ethical dimensions of medical care.
2. Development of policies and guidelines—Ethics committees in many facilities develop and propose institutional guidelines for decisionmaking for incapacitated patients and policies for Do-Not-Resuscitate (DNR) orders, treatment of handicapped newborns, and other difficult decisionmaking situations.
3. Consultation and case review—Ethics committees sometimes serve as a forum for discussing and resolving ethical and other concerns about specific cases; they may advise staff, families, or even patients about difficult treatment decisions; in some facilities they also re-

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[8] Kentucky, Massachusetts, Michigan, Minnesota, Nebraska, New Jersey, New York, North Dakota, Ohio, Pennsylvania, Rhode Island, and South Dakota (103).

> view treatment decisions and decisionmaking practices to ensure that the interests of all parties, especially decisionally incapable patients, have been represented (30).

The degree to which an institutional ethics committee serves each of these functions varies in different hospitals and nursing homes.

Despite widespread endorsement of ethics committees and the rapid growth in their numbers over the past few years, many questions remain about their role in medical decisionmaking vis-a-vis the legal system. One noncontroversial way that some ethics committees relate to the legal system is by providing physicians and other hospital or nursing home staff with information about recent developments in case and statutory law that are relevant to treatment decisions or decisionmaking procedures. Another relatively noncontroversial way that some ethics committees relate to the legal system is by advising health care providers that certain patients may need a legal guardian or that certain treatment decisions may require judicial review (72).

Far more controversial is the question of when, if ever, an ethics committee can function as a substitute for a court in a case that might otherwise require judicial involvement. The concept of ethics committees first received public attention as a result of the 1976 decision of the new Jersey Supreme Court in the *Quinlan* case, in which the court ruled that the decision to withdraw life-sustaining treatment could be made without judicial review if the institution's "ethics committee" agreed that there was no possibility that Karen Quinlan would return to "a cognitive, sapient state" (52). Despite its specific reference to an "ethics committee" and its statement that these committees could serve as "a more appropriate forum" than a court of law for the review of such ethical dilemmas (52), the *Quinlan* court actually assigned the committee a purely prognostic role—to determine whether there was any chance of Karen Quinlan's recovery (72). In the 1983 case, *In re Colyer* (45), the Washington State court delineated a similar role for what it referred to as a "prognosis committee" (2).

State courts have considered at least three cases in which institutional ethics committees were involved in aspects of treatment decisions other than establishing the patient's prognosis (116). In these three cases, the courts reached three different conclusions about the relationship between ethics committees and the courts.

In the 1977 *Saikewicz* case (109), the Massachusetts court indicated that ethics committee determinations may be admitted into a court case as evidence of the physician's good faith and proper standards of medical care (116). In contrast, in the 1984 Georgia case *In re L.H.R.* (50), the court ignored the determination of the ethics committee and said that there was no need for ethics committee consultation in this case or other similar cases. The court stated:

> In the case of incompetent adults who are terminally ill, in a chronic vegetative state with no reasonable possibility of regaining cognitive function, we find that the family of the adult or the legal guardian may make the decision to terminate life-support systems without prior judicial approval or consultation of an ethics committee (50).

Finally, in the 1984 Minnesota case *In re Torres* (56), the court considered the determination of several ethics committees that had been consulted and used them as evidence that a correct treatment decision had been made (116). In this case, the court said that ethics committees "are uniquely suited to provide guidance to physicians, families, and guardians when ethical dilemmas arise" (56) and that an ethics committee's determination that life support could be removed would eliminate the need for a court order.

It has been suggested that ethics committee review and approval of treatment decisions may minimize liability and reduce malpractice suits against the health care providers and facilities involved in such decisions (36,42,93,97). On the one hand, this suggestion might be taken to imply that the decision of an ethics committee would be accepted by a court as correct and would eliminate the need for court review, as in *In re Torres* (56). Some observers believe that ethics committees should not substitute for courts in this way because ethics committees' deliberations do not include the legal safeguards inherent in a court proceeding. According to one observer:

> Deferring to committees on the ultimate question of whether treatment should be forgone is . . . inappropriate. Committees operate under no uniform set of rules, and have no formal accountability. To defer to them on the resolution of cases involving foregoing treatment would be to carve out a class of important, life-and-death disputes that are deprived of any access to real court review: the court would merely rubberstamp the committee (116).

On the other hand, ethics committee review and approval of a treatment decision might be expected to minimize liability and reduce malpractice suits because ethics committees provide an institutional forum for discussion of treatment decisions. By involving all interested parties, such committees may decrease the possibility of misunderstanding or disatisfaction with the final decision and thus reduce the chance that one of the parties will take the case to court (36).

A third possibility is that ethics committee review and approval of a treatment decision might decrease the possibility of a successful law suit against a health care provider or facility because the court would consider the involvement of the ethics committee as evidence of the good intentions of the health care provider in the decisionmaking process, as in the *Saikewicz* case (109).

Whether institutional ethics committees actually reduce legal liability or the frequency of malpractice suits against health care providers or facilities involved in decisions about life-sustaining treatments is a question that cannot be answered with available data. Further analysis and research on the relationship between ethics committees and the legal system are needed.

Ombudsmen

"Ombudsman" is a Swedish term for a person who acts as a citizen representative. Under the Older Americans Act, States are required to have a Long-Term Care Ombudsman program. The ombudsman serves as an advocate for nursing home residents and is available to oversee and enforce their rights. Ombudsmen investigate complaints, and if necessary, they can initiate judicial proceedings. As discussed earlier, the *Conroy* court, sensitive to the potential for abuse in decisions to withhold or withdraw life-sustaining treatment from incompetent nursing home residents, ruled that the State Ombudsman for Institutionalized People must investigate and approve decisions to withhold or withdraw treatment from nursing home residents (46). This decision (as modified by 1987 decisions of the Court) applies only in New Jersey, and courts in other States have not defined a role for the State ombudsman in such decisions.

Professional Societies

Professional societies utilize the combined expertise, experience, and prestige of their members to develop and promote policies that affect the delivery of health care in general and all aspects of medical decisionmaking. In 1986, two professional organizations—the Los Angeles County Medical and Bar Associations—issued a joint policy statement regarding the withholding or withdrawal of life-sustaining medical treatment, for example (75). This collaborative effort between attorneys and physicians was intended to assist physicians faced with the legal and ethical dilemmas of life-support decisions and to educate attorneys and patients as to the issues presented by advanced medical technology.

Of more national prominence was the March 1986 policy statement of the American Medical Association (AMA) that endorsed the right of a patient or the patient's surrogate, if available, to make decisions about life-sustaining treatment and declared that artificial nutrition and hydration constitute treatment that can be discontinued in appropriate circumstances (1). Although this AMA statement is not binding on anyone, it is a strong statement from a prestigious organization, and it will most likely influence courts and legislators in their future decisions. Policy statements of the American Nurses Association; of national, State, and local hospital, nursing home, home care, and hospice associations; of the professional societies that represent physician specialists in critical care medicine and each of the five technologies discussed in this report; and of societies that represent allied health professionals who provide each of the technologies can also be expected to influence such decisions.

Institutional Policies for Decisionmaking

As discussed throughout this report, hospitals, nursing homes, and other health care facilities have developed institutional policies that define how decisions about life-sustaining treatments are to be made in the facility. Most such policies address decisions about resuscitation and DNR orders, but some facilities have limited treatment policies that apply to decisions about all kinds of life-sustaining treatments.

The relationship between institutional policies for decisionmaking and the legal system is unclear. Whether such policies provide legal protection for health care providers who follow them is not known. Moreover, there is disagreement about whether institutional policies for decisionmaking increase some legal risks for providers or facilities. Other questions also arise. What are the legal implications for facilities that institute a policy honoring living wills in States that do not have a living will statute, for example? An OTA report addressing these questions and other aspects of institutional policies for decisionmaking is in process and will be released in early 1988.

CRIMINAL LIABILITY

Physicians, like all professionals, are required by law to perform their duties according to certain standards of professionalism. If they fall below those standards and thereby harm their patients, they may be liable under civil law—that portion of the law that deals with relationships among individuals and groups. Criminal law—the portion of the law dealing with acts against the state defined in the criminal codes of the States and the United States and punishable by penalties described in the codes—has rarely been used for regulating physicians' conduct when they are engaged in good faith efforts to treat patients (5,118).

The few courts that have confronted the issue of using the criminal law to review whether a physician has properly practiced his or her profession have expressed great distaste for using the law for this purpose (5). In the 1976 Massachusetts case *Commonwealth* v. *Edelin* (28), for example, the court makes clear that only in the most extraordinary cases should the criminal law be used as a way to review the actions of physicians performing "professional tasks" and that the presumptions against criminality are very much in favor of a physician who acts in "good faith."

In considering cases in which prior judicial approval for withholding treatment is being requested, several courts have considered and rejected the possibility of a criminal charge. In the 1980 Massachusetts case *In re Spring* (54), for example, the court briefly discussed the concern physicians might have regarding criminal liability and concluded that:

> Action taken without judicial approval might be the subject of either criminal or civil liability. Little need be said about criminal liability: there is precious little precedent, and what there is suggests that the doctor will be protected if he acts on a good faith judgment that is not grievously unreasonable by medical standards (54).

There is only one reported case involving withholding or withdrawing life-sustaining treatment in which physicians have actually been accused of a crime—the 1983 California case, *Barber* v. *Superior Court* (10). That case concerned a patient, Clarence Herbert, who suffered a cardiac arrest following surgery and was placed on a mechanical ventilator. He had severe brain damage as a result of the cardiac arrest, and his physicians, Neil Barber and Robert Nedjl, informed his family that he was not expected to recover from his comatose condition. The family requested that he be removed from the ventilator. Two days later, when he had not died, the family asked that intravenous nutritional support and hydration be withdrawn. The physicians complied, and Mr. Herbert died in 6 days.

Mr. Herbert's physicians were subsequently charged with murder. The California magistrate who heard the evidence concluded that the physicians did not cause Mr. Herbert's death; that the physicians acted in good faith and exercised sound medical judgment; and that their state of mind did not constitute malice as defined in the California statutes on murder. Therefore, the charges were dismissed. The State appealed this decision to a Superior Court judge, who reinstated the charges, finding that regardless of the physicians' good faith and exercise of sound judgment, their actions were unlawful.

The California Court of Appeal overtuned the Superior Court ruling and found that charges of murder could not be brought against the doctors. The Court of Appeal commented:

> It appears to us that a murder prosecution is a poor way to design an ethical and moral code for doctors who are faced with decisions concerning the use of costly and extraordinary (life support) equipment (10).

The court concluded that cessation of life-support measures is not an "affirmative act" but is an "omission of further treatment" (10). It recognized that one can commit a crime by omission only if there is a duty to act. The question in the *Barber* case involved determining the physician's duty to an irreversibly comatose patient. The court concluded that "a physician has no duty to continue treatment, once it has proven to be ineffective" and that in a case in which the physician has made a "hopeless prognosis" based on accepted medical practice, and the patient's family wishes to discontinue treatment, such cessation of treatment, though intentional and with the knowledge the patient would die, does not constitute an unlawful failure to perform a legal duty (10).

The court recognized that the difficult issues are who is to determine that a patient's prognosis is hopeless and who is authorized to direct termination of treatment. It declined to give specific answers beyond indicating that such determinations are "essentially medical" and need to be made based on facts unique to each case (10).

The court did provide a general guideline for decisions about withholding or withdrawing life-sustaining treatment by stating that the benefits of treatment should exceed the burdens. Thus, the court said, the burdens of minimally painful or intrusive treatment may sometimes be disproportionate to the benefits if the prognosis is virtually hopeless. It therefore becomes the physician's task to make a diagnosis and prognosis based on accepted medical practice. Where possible, the patient should be the ultimate decisionmaker. When the patient is incapable, however, the family members are to make the decision based on what they believe the patient would want if able to express his or her own wishes (10).

Since the *Barber* case was the first instance in which physicians were charged with homicide for withholding or withdrawing medical care, it has caused tremendous concern within the medical community. Given this concern, a number of points must be made. First, the physicians prevailed; the charges against them were dismissed. Although one should not minimize the emotional toll legal proceedings take on the defendants, the reality is that the court supported the physicians' actions. Second, the *Barber* case never actually came to trial. All the legal proceedings that took place were designed to determine if the prosecutor could convict these physicians of homicide if he could prove the facts he alleged. The court did not conclude that the prosecution could not prove the facts, but rather that, even if proven, the facts did not support a charge of homicide. Third, the case was primarily concerned with the issue of the cessation of artificial nutrition and hydration, which was (and is) the most controversial area of the law. Even the district attorney was unconcerned about the removal of the ventilator. Fourth, it was family members who requested withdrawal, not the patient. There has never been a criminal action based on a patient's request to withhold or withdraw treatment. Finally, the court was very supportive of physicians, and expressed its displeasure at the use of the criminal process in this most sensitive area. It is extremely unlikely, after the *Barber* case, that any good faith cessation of medical treatment with the patient's or family's concurrence, could support a charge of homicide in the jurisdiction of the California court (5).

FINDINGS AND IMPLICATIONS

The common law right of self-determination guarantees the basic right of every individual to determine what shall be done with his or her body. The constitutional right of privacy protects the individual's right to make personal medical decisions. Although the U.S. Supreme Court has not addressed the question of whether the right of privacy includes a right to refuse life-sustaining medical treatments, several State courts have held that it does. Taken together, the right of self-determination and the right of privacy support the right of individuals to be informed about and to consent to or refuse proposed medical treatments.

The legal doctrine of informed consent requires physicians to disclose to a patient his or her diagnosis and prognosis, the proposed treatment, alternate treatments, the risk and benefits of all options, and the consequences of not intervening at all. With this information, the patient is expected to make a decision and instruct the physician how to proceed.

Exceptions to the informed consent requirement have been recognized for several situations, including emergencies and waiver situations in which the patient has expressed a desire not to receive the information. Some observers believe that elderly people are more likely than younger people to waive their right to informed consent. These observers argue that waivers of informed consent should require an explicit statement by the patient that he or she does not wish to receive the information and should not be based only on a tacit understanding between the patient and the physician.

Many problems interfere with implementation of the legal doctrine of informed consent. They include the fast pace of modern medical practice, the training and socialization of physicians in medical school, internship, and residency, and assumptions by some physicians and other health care providers that elderly patients in particular will not be able to understand the information.

Moreover, research indicates that informed consent as envisioned in the law is largely absent from clinical practice, that patients are seldom given information about proposed treatments before a decision about the treatment is made, and that even when patients are fully informed about proposed treatments, they act as if the doctor should make the decision (73). Research also indicates that the model of medical decisionmaking that underlies the doctrine of informed consent—a model that involves discrete decision points at which treatment options are clear and one can be selected—may be invalid in some clinical situations. Further analysis of the applicability of the informed consent doctrine to various decisionmaking situations is needed.

A patient's legal right to refuse unwanted medical treatment is a corollary of the right to consent to medical treatment. Strong as it may be however, the patient's right to refuse treatment is not absolute. Four societal interests have been identified by courts as potentially worthy of overriding a patient's right to refuse treatment:

1. the preservation of human life,
2. the protection of third parties,
3. the prevention of suicide, and
4. the protection of the ethical integrity of the medical profession.

Only rarely, however, have societal interests been used by courts to justify the use of unwanted medical treatments.

With regard to the societal interest in the protection of the ethical integrity of the medical profession, however, courts have handed down contradictory rulings about whether health care providers and facilities must participate in withholding or withdrawing treatment when such participation violates their convictions. Further legal debate on this question is expected.

In practice, hospital patients who wish to refuse medical treatment confront a strong institutional commitment to curing disease and preserving life. Hospital and nursing home patients may experience a feeling of loss of control associated with institutionalization and may fear that they will be abandoned by their caregivers if they refuse recommended treatment. Finally, although American law presumes that adults are competent unless a court has determined that they are incompetent, health care providers and others often assume that elderly persons, particularly those who are severely ill or debilitated, are incapable of making decisions. For each of these reasons, patients may experience difficulty in refusing unwanted treatment.

A great deal of confusion and controversy surrounds the issue of determining decisionmaking capacity in persons whose decisionmaking capacity is questionable or fluctuating. It is generally agreed that decisionmaking capacity should be determined in relation to a specific treatment decision and that the tests of decisionmaking capacity should be based on the values of patient autonomy and patient well-being. Yet the specific tests that have been proposed reflect differing societal judgments about the relative importance of these two values.

There is also controversy about the appropriate role of the courts in determining decisionmaking capacity. Some observers believe that it is seldom necessary or advisable to turn to the courts for a determination of decisionmaking capacity. Others believe that a court hearing is the appropriate forum for such determinations, especially when health care providers disagree among themselves or disagree with family members about a patient's decisionmaking capacity.

Courts have ruled that elderly people who are decisionally capable have the same rights as other adults to consent to or refuse medical treatment. Elderly people who are decisionally incapable are also considered to have the same fundamental rights. Case law and statutes in different States provide several methods for designating a surrogate decisionmaker for persons who are decisionally incapable. These include durable power of attorney, guardianship, and family consent statutes. In addition, some living will statutes allow individuals to appoint a surrogate decisionmaker in advance of becoming decisionally incapable. In practice, however, most decisionally incapable patients do not have a surrogate designated by any of these methods, and health care providers usually obtain consent for proposed treatments through informal discussions with family members or friends of the patient. Although this informal method frequently works well, it is potentially fraught with difficulties if family members or others disagree about who should be the surrogate decisionmaker or about whether a specific treatment should be provided. Increased use of formal methods for designating a surrogate decisionmaker could provide greater protection from legal liability for health care providers and at the same time provide greater assurance that someone is explicitly designated to exercise the patient's right to consent to or refuse proposed treatments.

Courts have identified two standards for surrogate decisions—best interests and substituted judgment—again based on the values of patient autonomy and patient well-being. The substituted judgment standard requires the surrogate to use the patient's personal preferences and values for health care decisions. The best interests standard requires the surrogate to make a decision from the perspective of a hypothetical "reasonable person," considering factors such as the usefulness or futility of the proposed intervention and its risks, benefits, and burdens.

Courts have generally preferred the substituted judgment standard, provided there is evidence of the patient's preferences. Courts in different States have differed, however, on what constitutes acceptable evidence. Prior declarations of patients made while they were still decisionally capable, including living wills, have been regarded as the best evidence of the individual's preferences. In the absence of a prior declaration, courts have looked to the values of the patient and opinions of relatives and friends about the individual's likely preferences.

Whether a court must review surrogate decisions for decisionally incapable patients varies in different States as a result of court rulings in each State. Whereas some courts have determined that judicial review is required at least in some circumstances, other courts have ruled that these decisions may be made without court review as long as certain procedures are followed. Inconsistencies in court rulings on this issue result in uncertainty among health care providers about the required decisionmaking procedures and intensify their fear of legal liability when life-sustaining treatment is withheld or withdrawn.

Living wills provide an explicit expression of a patient's preferences about life-sustaining treatments. Although 38 States and the District of Columbia have now enacted legislation authorizing living wills, there is considerable variation among States in the form and procedures required to execute a valid living will, the specific medical treatments that may be withheld or withdrawn pursuant to a living will, and the condition of the patient that warrants nontreatment (i.e., the definition of terminal illness). Because of differences among States in the provisions of their living will statutes, living wills that are valid in one State may not be recognized in another State. Only four States specifically recognize living wills from other States.

In addition to problems with living wills that may arise because of the lack of uniformity among States, reservations about living wills include the concern that individuals may not be able to accurately predict what their treatment preferences will be at an undetermined time in the future, that living wills are not sufficiently specific to direct treatment decisions and that they do not allow individuals to request as well as refuse treatments. A durable power of attorney for health care can meet each of these objections, and many commentators favor the durable power of attorney over the living will as a method of assuring that an individual's treatment preferences are known if he or she becomes decisionally incapable. Some commentators suggest that the best approach may be a living will that includes the designation of a surrogate decisionmaker. Living will statutes in a few States specifically allow the designation of a surrogate decisionmaker.

Guidance in decisions about withholding or withdrawing life-sustaining treatment is provided in some circumstances by nonjudicial consultative sources. These sources include ethics committees in some hospitals and nursing homes, guidelines for decisionmaking issued by professional societies and associations that represent health care facilities, and institutional policies for decisionmaking. Many questions about the specific legal import of these sources remain unanswered.

There is general agreement that the criminal law is not an appropriate context for judicial review of physicians' decisions about life-sustaining treatment. In the single case in which physicians have been accused of a crime for withdrawing life-sustaining treatment, *Barber* v. *Superior Court*, the California Court of Appeal dismissed the charges, concluding that withdrawal of treatment can only be a crime if the physician has a duty to act, and that a physician does not have a duty to act if the treatment is ineffective, the prognosis is hopeless, and the family wishes to discontinue treatment. The *Barber* court and several other courts have expressed great distaste for using criminal law to review the decisions of physicians acting in good faith.

From the discussion in this chapter, it is clear that, in general, decisionally capable adults have a legal right to consent to or refuse proposed medical treatments and that such treatments may be legally withheld or withdrawn from decisionally incapable adults under some circumstances. Nevertheless, there is uncertainty and disagreement about some aspects of the law relevant to these treatment decisions. Areas of consensus and consistency between States appear to be increasing. Yet inconsistencies in court rulings and statutes in different States, and sometimes in court rulings in the same State, make it understandable that health care providers are unsure about their legal obligations to patients and their permissible range of action.

In addition to the fundamental question as to whether the constitutional right of privacy includes a right to refuse life-sustaining treatment and to the very controversial legal issues pertaining to withholding or withdrawing nutritional support and hydration that are discussed in chapter 8, the primary areas of uncertainty are:

- the application of informed consent doctrine in clinical situations in which decisionmaking is virtually continuous and discrete decision points are not obvious,
- the appropriate criteria and procedures for determining decisionmaking capacity,
- the methods by which individuals may express their preferences about life-sustaining

treatments in the event that they become decisionally incapable in the future, and

- the appropriate criteria and procedures for surrogate decisionmaking for individuals who have not executed advance directives.

Each of these areas requires further analysis, discussion, and debate involving both legal experts and the physicians, nurses, and other health care providers who care for critically and terminally ill and severely debilitated patients on a daily basis.

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Chapter 4
Ethical Issues

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Chapter 4

Ethical Issues

INTRODUCTION

Modern science has brought about dramatic changes in medical care, particularly since the early 1950s, and technology now gives people considerable power to alter both the quality and length of human life. However, the use of life-sustaining technologies such as the five examined in this assessment—resuscitation, mechanical ventilation, dialysis, nutritional support, and life-sustaining antibiotics—raises many important ethical questions. Society thus finds itself asking difficult questions about individual rights, the processes of living and dying, and the proper distribution of technological resources. The use of life-sustaining technologies necessitates the development of an ethical vision that is acute enough to discern the needs and wants of particular individuals and yet wide-ranging enough to guide contemporary public policy. This chapter explains some of the major ethical debates that have occurred in the public, academic, and clinical domains about these issues.

Ethical analysis can help clarify ethical dilemmas. Such dilemmas occur where any possible solution to a problem seems to involve some type of harm or where it only seems possible to achieve a good outcome through the use of unethical means. In these difficult cases, ethical analysis may not point definitively to one and only one "right" answer, but it can clarify competing systems of justification for certain courses of action. It can also show where different principles or methodologies for decisionmaking are needed. (For an international list of organizations specializing in ethical analysis, see app. D.)

The Relationship Between Ethics and Law

It is a fact of life in our society that an emerging moral or ethical consensus may not be embodied in existing statutes and that the legal system may actually pose barriers to the resolution of ethical dilemmas. Nonetheless, legal cases in which the rights and interests of competing parties are adjudicated provide public access to the analysis of competing points of view. These points of view often consist of important ethical arguments.

The growth of newer types of deliberative bodies such as institutional ethics committees provides an important alternative or adjunct to the legal system. A terminally ill elderly person, for example, cannot wait for the results of a protracted legal battle to evaluate his or her claims and preferences for or against life-sustaining treatment. In addition, the establishment of a legal precedent concerning one use of a particular life-sustaining technology may not be relevant or meaningful in other cases. Certain features of the legal system may make it difficult to resolve the ethical dilemmas associated with the use of life-sustaining technologies.

Ethics in Clinical Practice

The growing role of ethicists and ethics committees in health care settings is an important development. Several State courts have specified a role for institutional ethics committees in all decisions to withdraw or withhold life-sustaining

Photo credit: Hennepin County Medical Center, Minneapolis, MN

Biomedical ethics committee at work.

treatment (see ch. 3). Ethics committees can provide an opportunity for multidisciplinary input regarding problems that require several types of expertise and their membership can represent the plurality of values present in American society. Committee deliberations can build consensus that may also be helpful to patients and their families at times of crisis. Reservations about the utility of ethicists and ethics committees usually center on the way in which their input will be used and the amount of authority that will be given to their recommendations. Guidelines about the roles of ethicists and ethics committees are still in an early phase of development (17).

ETHICAL ISSUES IN THE CARE AND TREATMENT OF INDIVIDUAL PATIENTS[1]

Four ethical principles are of great use in analyzing dilemmas concerning the use of life-sustaining technologies:

1. Beneficence = being of benefit to others;
2. Nonmaleficence = not harming—including not killing—others (sometimes viewed as a subset of the principle of beneficence) (26);
3. Respect for persons = treating others as ends in themselves and showing regard for their autonomy (sometimes called the principle of respect for persons or the principle of autonomy); and
4. Justice = treating others fairly according to principles of equity in the distribution of benefits and burdens.

Other independent or derivative principles have been recognized, including privacy, truthfulness, and fidelity in keeping promises and contracts (6,42).

Because of the strong prohibitions that are derived from the second principle, which in the Hippocratic tradition of medicine is interpreted as "first or at least do no harm," both suicide and mercy killing are generally prohibited in our society. Death is viewed as a major—often the major—harm, and thus deliberately engaging in actions that bring about, hasten, or cause death is an obvious wrong as a violation of the principle of nonmaleficence. This principle is so important that most traditions tend to justify killing persons only in self-defense, war, and capital punishment. Most traditions tend to view acts that cause the deaths of innocent persons, even those who are suffering greatly, as justifiable only if they do not involve the direct *killing* of those persons.

In decisionmaking about life-sustaining technologies, distinctions are sometimes made between *withholding v. withdrawing treatment*, *direct v. indirect effects* of actions, *letting die and killing*, and *ordinary and extraordinary* means of treatment. These distinctions are analyzed below.

Withholding v. Withdrawing

Physicians, nurses and other health care providers often feel that the distinction between *withholding* (not starting) and *withdrawing* (stopping) life-sustaining technologies is very important, even though it is hard to defend in terms of various ethical traditions. The following case illustrates the appeal of this distinction:

Case 1: An elderly man was suffering from several major medical problems, including terminal cancer, with no reasonable chance of recovery. The patient was clearly incompetent and could not communicate with others; he had no family to serve as surrogate decisionmakers. The members of the staff caring for the patient had easily and quickly agreed on a "no code" or "do not resuscitate" (DNR) order. They felt comfortable with this decision because of the patient's overall condition and prognosis and because not resuscitating the patient in the event of cardiac arrest could be viewed as withholding rather than withdrawing treatment.

The patient was being maintained by intravenous nutrition and hydration and was receiving antibiotics to fight infection. Several members of the team thought that all medical treatment, including artificial nutrition, hydration, and antibiotics, should be stopped, but others thought that it would not be right to stop these treatments. However, when an intravenous line slipped out of place, some of the latter group concurred that

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[1] This section is based in part on a paper prepared for OTA by James F. Childress, 1985 (14).

it was not obligatory to start the line again, especially if it involved a more invasive insertion procedure, because this could be viewed as *starting* rather than *continuing* a treatment. Others sharply criticized this use of the distinction between withholding and withdrawing treatments on the grounds that it was a self-deceptive rationalization (14).

Perhaps the clearest rationale for the distinction between withholding and withdrawing treatments is that in initiating a life-sustaining treatment, a physician or other health professional makes a promise, or engenders expectations, which, on grounds of fidelity or loyalty to the patient, require that the treatment not be stopped. An opposing view, however, is that a physician's fundamental promise is to act in accord with the patient's wishes and interests (the principles of beneficence and respect for persons), and this can override the original or implied promise to the patient.

Some professionals reportedly have been reluctant to start treatments in some circumstances for fear of being locked into their continuation. Yet, it is often necessary to start life-sustaining treatments to gain time and information for better diagnosis, prognosis, and decisionmaking. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research argued in 1983 that the burden of proof should be higher for withholding than for withdrawing treatment since a judgment about the latter could presumably be reached on more solid grounds (30). The Commission states "whatever considerations justify not starting should justify stopping as well." The Commission concludes that neither law nor public policy should mark a difference in moral seriousness between stopping and not starting treatment (30).

Direct v. Indirect Effects

The application of the distinction between *direct* (intended) and *indirect* (unintended but foreseen) effects of actions has often been used in the Roman Catholic tradition and in others to distinguish morally acceptable actions that have indirect, unintended, or merely foreseen effects such as death from morally prohibited actions of suicide or murder. Traditionally the distinction between direct and indirect effects has involved four conditions: 1) the action in itself must be good or at least ethically neutral; 2) the agent must intend only the good effect and not the evil effect; 3) the evil effect cannot be a *means* to the good effect; 4) there must be proportionality between the good and evil effects of the action, that is, a proportionately strong reason for allowing the evil effect to occur. The evil effect is allowed, but not sought; it is foreseen, but not intended. This is called the rule of double effect (6,8,23).

Most often, the distinction between direct and indirect effects is invoked when there is a conflict between obligations or values and it is not possible to meet or realize all of them simultaneously. For example, a conflict may arise when, in the care of a terminally ill patient, the principle of nonmaleficence establishes a duty not to harm or kill the patient, while the principles of beneficence and respect for persons establish a duty to make the patient comfortable by relieving pain or inducing sleep. In some situations, it may be possible to make the patient comfortable only by engaging in actions that hasten the patient's death. According to the Ethical and Religious Directives for Catholic Health Facilities, "it is not euthanasia to give a dying person sedatives and such a measure is judged necessary, even though it may deprive the patient of the use of reason, or shorten his life" (37).

The rule of double effect thus distinguishes between relieving pain at the risk of bringing about death and relieving pain by bringing about death. According to some critics of the distinction, the question is not whether death is *intended* as an end or as a means, but *how* death is brought about. These critics assert that society has moral reasons for excluding some means of bringing about death, even if there is agreement among all the parties, including the patient, that he or she would be better off dead.

Letting Die and Killing

Case 2: A 62-year-old patient was hospitalized for metastatic cancer of the colon. When it became clear that he would not likely benefit from

either chemotherapy or radiation, the patient refused further laboratory tests, antibiotics, transfusions, and dialysis, while accepting pain medication, nasogastric suction, and intravenous fluids. Four days later he asked doctors to "speed up" his death, less because of his pain and discomfort and more because he could not endure the dying process any longer and did not want to jeopardize his family's limited financial resources. The staff gave substantial doses of morphine and diazepam, with the agreement of the patient and family (20).

This case cannot be brought under the rule of double effect for "allowed deaths"; the medication was not given to relieve pain at the risk of hastening death. It was not a case of letting the patient die but rather one of directly and actively killing the patient at his request by the administration of toxic drugs.

Sometimes the distinction between killing and letting die is discussed under other headings, such as omission and commission or passive and active, because it is argued that more descriptive terms are needed to replace "killing," which most people tend to view as wrong, and "letting die," which most tend to view as right. Thus, the President's Commission (30) used the descriptive phrases: *actions that lead to death* and *omissions that lead to death*. Whatever terms are employed, the issues are the same.

Most ethical traditions have a rule prohibiting the direct, active killing of patients, even though they disagree about the foundations of that rule. Some traditions hold that it is intrinsically wrong to kill innocent persons; others hold that it is not intrinsically and absolutely wrong to do so, for example, when the suffering patient requests "mercy killing," but that a rule prohibiting mercy killing is necessary to prevent bad consequences for future patients and ultimately for the society. Thus, many people who deny that acts of killing innocent persons are always wrong still support a rule of practice that prohibits such acts because of the dangers of abuse, loss of trust between professionals and patients, and subversion of the societal commitment to the protection of human life.

Some critics hold that there is no intrinsic ethical difference between killing and letting die and that "letting nature take its course" is not appropriate when interventions are available. These critics argue that whether there is an ethical difference between killing and letting die will depend on the circumstances of the case. Thus, in a widely discussed article, one philosopher contends that the "bare difference" between acts of killing and acts (omissions) of letting die is not in itself an ethically relevant difference. He argues his point by sketching two cases that differ only in that one involves killing, while the other involves allowing to die, and asks whether we would make different ethical judgments about the cases (31). In those cases—killing a 6-year-old cousin or letting him die to gain a large inheritance—both acts are equally reprehensible because of the agent's motives, ends, and actions or inactions.

But reprehensible illustrations may obscure the significance of the distinction in other cases where agents are trying to benefit (rather than harm) patients and where they are also concerned about broader social consequences and protecting society's commitment not to let innocent people be killed. Although the distinction between killing and letting die may not be important in some contexts, this distinction may be important in other cases, because of other moral principles and rules.

The prohibition against direct, active killing of innocent persons is built into the legal system as well as into professional codes and religious and humanistic traditions. Arguments to change this rule often appeal to cases of extreme, intractable pain and suffering, usually related to a slow death from cancer. According to critics of the rule, a failure to kill a patient in circumstances where the patient pleads for "mercy" is cruel and inhumane.

Several counterarguments have been offered, however. First, it is not clear that there are many cases of uncontrollable pain and suffering; in the medical setting (perhaps in contrast to the battlefield or an accident) pain can usually be controlled, although its relief may hasten death (which is acceptable according to the rule of double effect). A second argument is that permitting mercy killing will divert attention from finding methods short of killing, for example, institutional and social options such as hospices that can reduce the pain and suffering to tolerable levels and permit compassionate social and personal attention from the community.

Since the need to change society's standard in order to allow mercy killing to relieve pain and suffering is uncertain, and since such a change presents potential dangers to society through abuse, decline of trust within medical relationships, and the threat to the principle of nonmaleficence that prohibits killing, there do not appear to be sufficient reasons to change the prohibition against killing. Some people argue that the burden of proof should be on those who would maintain a rule that infringes on the principle of autonomy. However, it is plausible to argue that the policy and practice of prohibiting killing (while accepting some cases of allowed deaths) has served society well, though not perfectly, and that the burden of proof should rest on those who argue for changing it. Many commentators contend that this burden has not been met (6).

In addition, there are ways to "accept" some exceptional cases of mercy killing without changing the current legal and social prohibition—e.g., prosecutorial discretion, jury findings of not guilty by reason of temporary insanity, and recognition of "mercy" as a factor that mitigates punishment even though it may not exculpate the agent. Even with these informal exceptions, the rule may serve as a valuable reminder of the principle of nonmaleficence (first of all do no harm). Although some people argue that a regulatory scheme to assure that the patient really wants to die would prevent abuses, the formalization of such a process would have its own costs because it would involve society prospectively and directly in choosing and implementing mercy killing.

Even if the distinction between killing and letting die is accepted as a social and legal rule, debates will continue about where the line should be drawn between the two concepts. It is not sufficient to point to the categories of active and passive or acts and omissions. Nor is it simply a matter of identifying the cause of death because identifying "the cause" in ethical and legal settings is in part a moral as well as an empirical matter. Some ambiguity and uncertainty about the line between killing and letting die will always exist and different health care professionals and others will draw it in different places, as was shown in Case 1. However, there are some clear cases of direct, active killing, such as Case 2, and it is not unreasonable to continue to prohibit them even as society continues to assess where the line should be drawn.

Ordinary and Extraordinary Means of Treatment

Originally formulated in Roman Catholic moral theology, the distinction between ordinary and extraordinary means of treatment has been widely adopted in other ethical traditions and in legal decisions and professional codes. For example, after rejecting mercy killing or the "intentional termination of the life of one human being by another," the American Medical Association House of Delegates in 1973 held that the patient and/or his immediate family can decide about the "cessation of *extraordinary means* to prolong the life of the body when there is irrefutable evidence that biological death is imminent" (1).

The distinction was originally used to determine whether a patient's refusal of treatment should be classified as a suicide. Refusal of "ordinary" means of treatment was viewed as suicide, whereas refusal of "extraordinary" means was not viewed as suicide; withholding or withdrawing "ordinary" means from a patient was homicide, whereas withholding or withdrawing "extraordinary" means was not considered homicide.

According to one interpreter of the distinction, *ordinary* means are all medicines, treatments, and operations that offer a reasonable hope of benefit for the patient and that can be obtained and used without excessive expense, pain, or other inconvenience (19). *Extraordinary* means are all medicines, treatments, and operations that cannot be obtained or used without excessive expense, pain, or other inconvenience, or that, if used, would not offer a reasonable hope of benefit. The distinction does not refer to properties of medical practice or of the technologies themselves. Rather it hinges on two criteria: whether any particular medical treatment offers a reasonable chance of benefit and whether its probable benefits outweigh its probable burdens, including expense and pain.

The language of ordinary and extraordinary means is subject to criticism because it focuses attention on customary medical practice and technologies rather than on underlying principles and values. Hence technologies are sometimes viewed as ordinary if it is usual or customary for physicians to use them for certain diseases or problems and extraordinary or heroic if use is not customary. The patient as a person often disappears from view. Several other criteria have been invoked to distinguish ordinary from extraordinary means of treatment: their simplicity (simple/complex), their naturalness (natural/artificial), their expense (inexpensive/costly), their invasiveness (noninvasive/ invasive), their chance of success (probable/improbable), and their balance of benefits and burdens (proportionate/disproportionate). It is alleged that a technology that meets the first of the paired terms is closer to ordinary, while one that meets the second of the paired terms is closer to extraordinary.

Some ethicists propose to replace the terms ordinary and extraordinary with other terms that are less misleading (33,40). "Ordinary" could be redefined to mean morally obligatory, mandatory, required, or imperative, while "extraordinary" could be used to mean morally optional, elective, or expendable. These terms seem to reflect the practical point of the distinction more clearly. But if the new meanings are accepted, there is still the question about which criteria can adequately distinguish obligatory from optional treatments in particular circumstances.

If the criteria that distinguish ordinary from extraordinary appear to be relevant in a given case, it may be because they express other principles and values, such as acting in accord with a patient's wishes (the principle of autonomy) and in accord with a patient's interests (the principles of beneficence and nonmaleficence). For example, if an available treatment is simple and natural but not in accord with a patient's wishes and interests, it is hard from the patient's perspective to see why it should be handled differently than another treatment that is complex and artificial. Furthermore, many of the criteria are unclear. According to one study conducted after the Natural Death Act was implemented in California, physicians in that State generally viewed mechanical ventilation, dialysis, and resuscitation as "artificial," but split evenly on intravenous feeding. Two-thirds viewed insulin, antibiotics, and chemotherapy as "natural" (35). Other criteria, such as the degree of invasiveness (noninvasive/invasive) and cost (expensive/costly), may be ethically relevant in view of the patient's overall condition, interests, and preferences.

The main consideration for many ethical traditions is consistent with what has been called the criterion of "proportionality":

> Is it necessary in all circumstances to have recourse to all possible remedies? In the past, moralists replied that one is never obliged to use "extraordinary" means. This reply, which as a principle still holds good, is perhaps less clear today, by reason of the imprecision of the term and the rapid progress made in the treatment of sickness. Thus some people prefer to speak of "proportionate" and "disproportionate" means. In any case, it will be possible to make a correct judgment as to the means by studying the type of treatment to be used, its degree of complexity or risk, its cost and the possibilities of using it, and comparing these elements with the result that can be expected, taking into account the state of the sick person and his or her physical and moral resources (37).

In general, the distinctions between withholding and withdrawing, direct and indirect effects, killing and letting die, and ordinary and extraordinary means do not provide ethical answers, although they may reflect important ethical considerations. Whether these distinctions are valuable will depend then on whether they illuminate or distort the relevant ethical considerations that have been identified as part of a widespread consensus in a pluralistic society. According to several ethical traditions, the relevant considerations are the patient's wishes and interests, in light of his or her condition and in view of the overall societal allocation of resources and the necessity of some societal rules, such as the prohibition of killing.

Levels and Kinds of Care

Some commentators suggest that distinctions between levels and kinds of technologies have ethical implications. In an article on the physician's responsibility to "hopelessly ill" patients, the authors distinguished the following levels of care:

1. emergency resuscitation;
2. intensive care and advanced life support, including mechanical ventilation;
3. general medical care, including antibiotics, dialysis, and artificial hydration and nutrition; and
4. general nursing care, including pain relief, hydration, and nutrition for patient comfort (43).

The five technologies that are the subject of this report—resuscitation, mechanical ventilation, dialysis, nutritional support, and life-sustaining antibiotics—are at different levels in this hierarchy.

The application of distinctions between levels of care in withholding or withdrawing treatment is illustrated in the following cases, each involving a severely ill elderly patient.

Case 3: Mrs. X, a 79-year-old widow, had been a resident of a nursing home for several years. In the past she had experienced repeated transient ischemic attacks (brief neurological disturbance due to decreased cerebral blood flow). Because of progressive organic brain syndrome, she had lost most of her mental abilities and had become disoriented. She also had episodes of thrombophlebitis as well as congestive heart failure. Her daughter and grandchildren visited her frequently and obviously loved her deeply.

One day she was found unconscious on the bathroom floor. She was hospitalized, and the diagnosis was a massive stroke. She made no recovery, remaining nonverbal, but continuing to manifest a withdrawal reaction to painful stimuli and some purposeful behaviors. Mrs. X refused to allow a nasogastric tube to be inserted. At each attempt she thrashed about violently and pushed the tube away. After the tube was finally placed, Mrs. X pulled off her restraints and managed to remove it. After several days, her sites for intravenous infusions (IVs) were exhausted.

The question for the staff was whether to do further "extraordinary" or "heroic" measures to maintain fluid and nutritional intake for this elderly patient who had made no recovery from a massive stroke and who was largely unaware and unresponsive. After much mental anguish and discussion with the nurses on the floor and with the patient's family, the physicians in charge decided not to provide further IVs or a feeding tube, and to allow Mrs. X to die. She had minimal oral intake and died quietly the following week.

In Case 3, the family and staff decided to let Mrs. X die even though they could have prolonged her life for some time through artificial nutrition and hydration. One major issue in drawing lines is whether all medical treatments can be construed as "heroic" or "extraordinary" if they are out of proportion with the patient's wishes and interests. This question has been examined in several major court decisions and widely discussed (10,11, 12,22) in efforts to determine:

- whether nutrition and hydration by peripheral or central intravenous lines, nasogastric tubes, or gastrostomy tubes are more similar to other medical treatments, such as mechanical ventilation, or more similar to the provision of food and water by mouth;
- whether they are needed for comfort and dignity even when they are morally optional for the prolongation of life; and
- whether they so symbolize care and compassion that to withhold or withdraw them would threaten the foundation of humane and respectful medical care and, ultimately, social interaction.

If nutrition and hydration through medical means are similar to other medical treatments, then their use can be decided according to the criteria used for these other treatments. Critics of this position make several arguments. One argument is that medical nutrition and hydration are significantly different from other medical treatments because they are essential for comfort and dignity. However, some methods, such as central intravenous lines involve risks, and some may require that the patient be physically restrained. Another argument is that in withdrawing medical nutrition and hydration, the agent intends or aims at the patient's death (25). However, this intention may be present in other cases, such as removing the mechanical ventilator, and may not be inappropriate in all cases.

Probably the major criticism of failing to distinguish medical nutrition and hydration from other medical treatments stresses the symbolic significance of these activities, contending that the similarities among all acts of providing nutrition and hydration are so great that it is impossible to distinguish their *methods* (e.g., a gastrostomy from normal feeding). These acts are not only means to the ends of sustaining life and providing comfort; they also express the values of care and compassion.

Finally, concern about symbolic actions also leads several critics to believe that to accept the withholding or withdrawing of nutritional support and hydration, in *any* case, could lead to undesirable consequences for society as a whole. First, they believe even compassionate calls for withdrawing fluids in a few selected cases bear the seeds of great potential abuse. This fear arises if the act of withholding fluids is seen as a first step along a "slippery slope," where the standard of care shifts from actions in accord with the patient's interests to actions in accord with the society's interests, from the patient's quality of life to the patient's value for society, from dying patients to nondying patients, from letting die to killing, from cessation of artificial feeding to cessation of natural feeding, etc.

While these fears may be exaggerated, they have to be taken seriously, especially because of possible new threats of *undertreatment* as a result of cost-containment measures. This is a stark contrast to earlier threats of *overtreatment*. Simply stated, there is a danger that the "right to die" may become the "duty to die," even against the patient's wishes and interests (10). Although it is not clear that this danger can be avoided by mandating artificial nutrition and hydration in all cases, continuing fluids, even to dying patients, provides an important clinical, psychological, and social limit to acceptable withdrawals that some people believe should be retained (38).

Policies regarding cardiopulmonary resuscitation (CPR) have emerged separately and in some independence from policies about other life-sustaining technologies, such as mechanical ventilation. Decisions to provide—and decisions not to provide—CPR are often made without consultation in advance with patients or their families (2, 7,16,21). No one has adequately justified why decisions about CPR in hospitals are viewed as different from decisions about other life-sustaining technologies. Furthermore, it is often unclear to hospital personnel, as well as to patients and their families, what an order not to resuscitate means, if anything, about other levels of care and other technologies. For example, some patients with DNR orders still receive chemotherapy, surgery, and admission to the intensive care unit (ICU), while others do not receive even supportive care (16). It may be appropriate to indicate very concretely what will be provided in case of cardiac arrest and which medical and supportive efforts will be continued and which will not after a DNR order has been given.

The following case illustrates some of the moral and practical difficulties in respecting patients' wishes and meeting their needs:

> **Case 4: A 79-year-old widow experienced recurrent congestive heart failure and chronic obstructive lung disease. During one hospital admission, she had "absolutely refused" to be intubated (have a breathing tube inserted into her windpipe) ever again. She was readmitted to the hospital for 5 days after another period of crisis. Only 2 days after being discharged, she was again readmitted to the hospital. She repeated her wish not to be intubated, although she was willing to receive basic CPR if necessary. Serious problems of pneumonia, absence of urination and episodes of irregular heartbeat developed. On the 21st hospital day, she said that intubation "might be considered." When lucid, she sometimes "wasn't sure" about intubation, and, at other times, the patient did not want intubation. On day 25, shock, lack of oxygen, and abdominal swelling developed. Because there were potentially reversible causes for the deterioration of her condition, the physicians intubated her, administered vasopressor medications to lower her blood pressure, and transferred her to the intensive care unit. On the 31st day, she responded unambiguously and consistently with head nodding that she wanted mechanical ventilation and maximal care. Her condition worsened. On day 40, she was comatose and still required mechanical ventilation and**

vasopressor therapy. The physicians judged that no reversible disease was present. With the concurrence of her son, treatment with vasopressor agents was discontinued, a DNR order was written, and she was allowed to die (21).

When a patient's wishes and interests are considered, important distinctions can be drawn regarding levels and types of care, pertaining both to the range of CPR procedures and to other treatments. However, these distinctions cannot be assumed to hold in all cases because, as Case 4 indicates, medical treatments as such are not always obligatory. Whether they are obligatory or optional in a particular case is a judgment call based on the patient's wishes and interests in the context of a just allocation of societal and hospital resources and social rules to prevent unacceptable consequences.

Major Considerations in a Typology of Withdrawing and Withholding Life-Sustaining Medical Treatment

In proposed typologies of withholding and withdrawing life-sustaining medical treatment, the following issues are among the most important (14):

- How is death brought about?
- Who brings it about?
- Who decides?
- Why is death brought about?

The major distinctions discussed so far have focused primarily on *how* death is brought about. Although "euthanasia" is sometimes defined by its etymological roots (from the Greek, eu + thanatos = good or easy death), its more common, contemporary usage denotes "mercy killing." The terms "active euthanasia" and "passive euthanasia" are sometimes used. The distinctions between direct and indirect effects and ordinary and extraordinary means are also relevant to possible typologies of withholding or withdrawing life-sustaining technologies.

Despite some overlap, there is an important distinction between *who acts* and *who decides*. Some analysts ignore the distinction between agents who act and concentrate on agents who decide; thus, Mayo (24) insists that "voluntary active euthanasia is assisted suicide," and Tonne (39) suggests that the term "suicide" should be replaced by the term "autoeuthanasia." However, it is as important to preserve the distinction regarding who acts as it is to preserve the distinction in decisionmaking; who acts is important in distinguishing suicide from other actions. The line between "assisted suicide" and "voluntary, active euthanasia," which both involve killing, is determined by who is the final actor, the patient or someone else. However, the question of who decides remains important in cases of "euthanasia" or "mercy killing," which may be voluntary or involuntary from the standpoint of the patient.

Finally, it is also important to consider the grounds of the decision—the *why* of the decision—regardless of who makes it and carries it out. The major distinction is between reasons based on the patient's interests and reasons based on the interests of others, such as the family or society. These reasons are not always incompatible, but possible tensions should be noted, particularly when a decision is made by someone other than the patient for the interests of parties other than the patient. Thus, it may be necessary to develop procedures to protect patient decisionmaking and patient wishes and interests (as discussed in several places in this report).

Too many variables are involved in decisions about withholding or withdrawing life-sustaining treatments to permit tight and illuminating typologies. But important themes can be used to describe and evaluate various acts, some of which will also appear in the discussion of suicide and its relation to the refusal of life-sustaining treatments.

Defining Suicide and Its Application to Cases of Elderly People Receiving Life-Sustaining Technologies

Growing attention is being paid to the idea that individuals may want to exert direct control over the timing of their deaths by withdrawing life-sustaining technologies or by taking specific medications in lethal amounts (13). The empirical relationship between the use of the life-sustaining technologies and deliberate deaths cannot be quantitatively described because no data are available. In addition, important conceptual problems need to be considered in order to talk about suicide and assisted death in meaningful ways.

There is no clear, neutral, widely accepted definition of "suicide." Suicide is always defined within traditions that make normative as well as conceptual points—the definitions are intended to guide behavior. For example, some traditions hold that suicide is always wrong and then sharply distinguish acts of suicide from other acts that lead to one's own death. Other traditions hold that suicide can be justified under some circumstances and thus do not worry as much about the line between suicide and other acts that cause one's own death. Justified exceptions to a rule prohibiting suicide within one tradition may be built into the definition of the rule in another tradition. For example, one tradition might justify acts of suicide to save others, while another tradition might hold that acts that are intended to help others rather than to bring about one's own death (such as falling on a grenade to save one's comrades) are not really acts of suicide and thus do not violate the rule against suicide.

At the very least, the concept of suicide involves: 1) a person's death, and 2) that person's involvement in his/her death. For an act to be considered a suicide it is necessary for a person to have intentionally brought about his or her own death, but these criteria are not sufficient to define suicide.

The questions and distinctions developed in the previous section suggest some key points: *Who decides?* In suicide, the one whose death is brought about makes the decision for death. *Who acts?* In suicide, the final actor, however much assistance is involved, is the one whose death is brought about.

Case 5: A 75-year-old woman, suffered from ovarian cancer. Her physicians indicated that she had only a few months to live, that chemotherapy would not arrest the cancer, and that her dying would be very painful. The chemotherapy made her bald and resulted in constant nausea and vomiting. She indicated to her daughter that she wanted to commit suicide and asked for her daughter's assistance in making it as efficient and painless as possible. The daughter secured the pills and passed on a doctor's instructions about how they should be taken. When the daughter expressed reservations about what they were doing, her husband reminded her that they "weren't driving," but that her mother was, and that they were only "navigators" (36).

As these metaphors suggest, in suicide the person whose death is brought about both decides *and* acts. If the agent did not decide and act voluntarily, that is, apart from coercion by others, the act of killing oneself would not be an act of suicide (5). Nevertheless, disputes arise, particularly about determining the intentionality of the act. At the very least, knowledge that an action will probably bring about one's own death is usually sufficient for suicide.

How is death brought about? In some religious traditions, when death is brought about by letting nature takes its course rather than by killing, by indirect rather than by direct means, and by forgoing extraordinary rather than ordinary procedures, the act is not considered suicide, especially if death from disease is inevitable and imminent whatever is done. In general, the more active the means of bringing about death and the closer the temporal association between the action and the death, the more likely the death is to be considered a suicide. Thus, several factors distinguish refusals of treatment from acts of suicide. These factors are:

- whether the person is already terminally ill so that death is imminent regardless of what is done;
- whether the means of death is active rather than passive and involves action rather than omission; and
- whether the death results fairly quickly after the action or omission.

Judgments about the role of these factors affect whether an act is considered negative (suicide) or neutral (refusal of life-sustaining treatment). For example, one commentator notes, "to the extent that we have unmistakable cases of actions by an agent that involve an intentionally caused death using an active means where there is a nonfatal condition, the more inclined we are to classify such acts as suicides; whereas to the extent such conditions are absent, the less inclined we are to call the acts suicides" (5).

Case 6: When Barney Clark at age 62 became the first human to receive a permanent artificial heart on December 2, 1982, he also was given a key that he could use to turn off the compressor if he wanted to die. As Dr. Willem Kolff noted, "If the man suffers and feels it isn't worth it anymore, he has a key that he can apply . . . I think it is entirely legitimate that this man whose life has been extended should have the right to cut it off if he doesn't want it, if life ceases to be enjoyable . . . " (32).

Although Clark's actions would have been vigorously debated if he had used the key to end his life, according to most of the criteria identified it appears that his act should have been characterized as a suicide without necessarily prejudging its morality. In some traditions, however, it is not possible to call an act suicide without simultaneously judging it negatively. Within such traditions, those who viewed the action as morally acceptable probably would take the position that the artificial heart was experimental and extraordinary and that Clark simply acted to end an experiment or to terminate an extraordinary treatment.

Why is death brought about? It is useful to distinguish two types of suicide or attempted suicide (a similar distinction would apply to refusals of treatment). In goal-oriented conduct, an agent attempts to realize some goal and bring about some effect or consequence. In suicides of this type, the language of cause and effect is very important; for example, an agent may attempt or commit suicide because of a belief that death is better than a life of pain and suffering or disability. In expressive acts of suicide—often attempted rather than actual—an agent conveys a meaning or makes a statement, such as a lack of hope or contempt for life or an appeal for help or attention. Some acts of attempted or successful suicide may be both instrumental and expressive.

Case 7: A 62-year-old artist committed suicide on June 9, 1979. Having learned in March 1978 that she had breast cancer which had spread to her lymph nodes, she underwent 10 months of chemotherapy before deciding to commit suicide. With the help of her family and friends, she fashioned her "life sculpture"—a pine coffin-like box filled with personal mementos, and then she wrote a farewell letter to 60 friends, said goodbye to her family, and swallowed 35 sleeping pills, washed down with champagne. Her family and friends cooperated.

This suicide illustrates both instrumental reasons (she believed that death was better than suffering from cancer and chemotherapy) and expressive reasons (she wanted to express her beliefs about "self-termination" and her conviction that "life can be transformed into art"). An autopsy indicated that her cancer had not spread beyond the lymph nodes to any vital organ (27).

Some traditions tend not to characterize sacrificial acts as suicide. However, there are limits; in Case 2, even if the patient had been able to secure and take the lethal medication himself, rather than having it administered by his physicians, his act would have been a suicide despite his other reason of not wanting to deplete his family's resources. Motives may be and usually are mixed.

ETHICAL IMPLICATIONS OF DISTRIBUTING LIFE-SUSTAINING TECHNOLOGIES[2]

In addition to the ethical distinctions involved in treating individual patients, there are significant ethical issues associated with the way in which life-sustaining technologies are allocated, shared, or distributed. The distribution of life-sustaining technologies is important because 1) such technologies may be scarce or expensive; and 2) the use of age as a criterion in allocation decisions has important implications for the hetergeneous group of people called the "elderly".

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[2] This section is based in part on a paper prepared for OTA by Robert M. Veatch, 1985 (41).

The problem of how to allocate resources ethically is usually referred to as a problem of justice. Justice is, however, a deceptively ambiguous term. In a general sense, justice means "the right." Thus, one might say that it is unjust to tell a lie. Justice in a narrower sense refers to fair distribution. It is in this second, narrower sense that justice can be examined in terms of the distribution of scarce life-sustaining technologies. Two important questions arise:

1. What are the major theories of a just distribution?
2. What are their implications for the use of age as a basis for allocating life-sustaining technologies?

The Interface Between the Ethics and Economics of Distributive Justice

The ethical issues raised by the use of life-sustaining technologies for elderly persons are closely related to the economics of their use. Economics, however, often only provides data about dollar costs per unit of benefit. It can, by extension, provide data about some other costs such as, social, psychological, and cultural costs. But economic analysis generally does not indicate how cost data ought to be assessed.

Theories of distributive justice are based on underlying sets of ethical suppositions. One might emphasize liberty and the rights that accrue with ownership of private property; another might emphasize the goal of maximizing aggregate net benefit, maximizing the position of the least well off groups, or striving for greater equality. Thus, even if there were complete agreement on the relative costs and benefits of alternative policy options, it would not necessarily be clear which policy should be adopted.

Increasingly, however, the critical ethical problems in health care will be distributive justice problems. Under most economic systems, persons ought to be permitted to refuse care that they do not find beneficial, provided that the refusal does not generate extra costs for society (and normally, it would not). The life-sustaining technologies that are the focus of this study sometimes offer only marginal benefit, but at great costs to third parties (insurers, hospitals, and governments). In these cases, the societal costs of care become a critical, *ethical problem*. Only by choosing a theory of distributive justice and integrating that theory into the calculations and analyses done to compare policy alternatives is it possible to decide how to respond to cases in which care is marginally beneficial and very expensive to third-party payers. How can goods be fairly distributed? Four major positions are responsive to this question: the libertarian, utilitarian, maximin, and egalitarian positions.

Major Theories of Distributive Justice

Libertarianism is one of a group of theories that spells out what persons are entitled to possess. These are sometimes referred to as entitlement theories. Libertarianism holds that persons are entitled to what they possess provided that they acquired it fairly (29). Fair acquisition includes gifts, exchange (including purchase), or original appropriation of previously unowned property. Heavily influenced by John Locke and the image of original appropriation from a state of nature, the libertarian position places great emphasis on individual liberty. Persons are permitted to do whatever they want with what they possess provided that they do not violate the holdings of others.

Utilitarianism, a second major position, holds beneficence or the maximizing of utility as dominant. The "right" pattern of distribution is one that produces the most good. That is the moral logic behind many policy analyses such as those using cost-benefit and cost-effectiveness analyses. These are economic methods for calculating the benefits and harms of alternative policies to determine which one will produce the greatest good *overall*. Thus, when a straightforward cost-benefit analysis is conducted it shows an implicit commitment to utilitarianism.

The libertarian and utilitarian patterns of distribution are obviously very different. What is striking, however, is that neither necessarily involves any redistribution to meet the needs of the poor, the sick, or the least well off, including the elderly (who may be poor, sick, and/or least well off). Libertarianism would permit such redistribution as a matter of charity. Utilitarianism would be open to redistributions to the poor if, and only if, redistributing resources increased the total amount of good in society. Such redistributions often increase the total amount of good because the harm that is likely to be done to the wealthy person is less than the good that could be done for poor persons. But there is no inherent moral principle that favors equality or redistribution on the basis of need.

Maximin theorists are concerned about those special cases where distributing things more equally or distributing in proportion to need will benefit the least well off. The most important maximin theorist is John Rawls, whose book, *A Theory of Justice* (34) has reoriented 20th century philosophical and public policy analysis of the problems of distribution. Rawls states that a group of rational, disinterested people would agree on two basic principles to guide the allocation of resources in a just society. These principles are:

1) Each person is to have an equal right to the most extensive basic liberty compatible with a similar system of liberty for others.
2) Social and economic inequalities are to be arranged so that they are both:
   a) to the greatest benefit of the least advantaged, consistent with the just savings principle, and
   b) attached to offices and positions open to all under conditions of fair equality of opportunity (34).

Since Rawls' second principle is designed to maximize the position of the least well off group, this theory of distribution is often referred to as the "maximin" theory. It holds that there is something ethically compelling about arranging resources so that the group on the bottom is as well off as possible, even if the result is that the amount of good per person is not as great as it could have been with some other distribution. The maximin position provides a powerful intellectual framework that overcomes some of the most severe problems with utilitarianism. Maximin theory, for example, squares with many people's moral intuition that slavery is wrong regardless of whether it may do more good than harm.

Egalitarianism is a coherent theory of justice as well as a theme within maximin theory. Maximin theory is one example of a theory of justice that places special emphasis on equality as a check against individual liberty and aggregate social welfare. It seems to be consistent with important religious and secular strands of Western thought. Some observers, however, have pointed out that maximizing the position of the least well off group does not necessarily require moving toward greater equality. In fact, maximin theory provides a framework for deciding precisely when inequalities are morally appropriate.

Several commentators distinguish between Rawls and other maximin theorists, on the one hand, and "true" or "radical" egalitarians on the other (3,4,28). True or radical egalitarians are committed in a straightforward manner to the goal of equality per se.

The important test case for separating maximin theorists and egalitarians is how they handle situations where the best way to improve the lot of the least well off is to devote substantial resources to talented elites to give them an incentive to use their skills to benefit those on the bottom (trickle down theory). Maximin theorists hold that in these circumstances, justice requires that the resources be given to the well off elites even though inequalities will actually increase. True egalitarians are distressed at the increases of inequality because they see great moral importance attached to equality as well as to increasing welfare.

Implications of Theories of Justice For the Use of Life-Sustaining Technologies With the Ill Elderly

The concept of "terminal illness" was defined in chapter 1 as an illness that has a *predictably* fatal progression that cannot be stopped by any known treatment. Terminal illness is distinguished from "critical illness" by the certainty of outcome. Many of the ethical dilemmas surrounding the use of life-sustaining technologies with elderly individuals arise from situations in which the patient is seriously ill and death is a possible outcome. The great uncertainty attached to the course of critical illness creates a crisis situation where decisionmaking is difficult and complex.

The *libertarian* perspective asks who would want and be able to receive life-sustaining treatment if free market forces and charity were the principal bases of access. Most life-sustaining technologies are sufficiently expensive that few people would have access to them, under a libertarian distribution scheme, unless they had personal financial resources or insurance coverage. Thus, a line would be drawn between elderly persons who either set aside money or purchased health insurance (presumably to supplement Medicare) to guarantee their access to treatment. Additional divisions could be seen among those elderly persons who buy health insurance, according to the level and type of coverage they choose. For example, some persons would choose a health insurance policy that provides coverage during terminal illness, while others would not want such coverage. Some would choose coverage for long-term care, while others would view as sufficient coverage for hospital care. Some would consider their benefits under Medicare sufficient.

There are problems with this position, however. Most people would at least want life-sustaining technologies if they relieved pain and suffering and relieved it at a relatively low cost. Some might also desire more aggressive treatment, but the libertarian approach would require them to compare the benefits of having the insurance coverage with the benefits of having the money needed to buy that coverage to spend on something else. It is likely that a great many people would forgo the coverage, especially coverage beyond that necessary to provide comfort. They would probably be more willing to buy coverage for life-sustaining technologies that were relatively inexpensive. In addition, while failure to purchase health insurance is sometimes a fair statement of an individual's evaluation of the benefits, it frequently is not. Many people who would opt for life-sustaining treatment may end up without it because they do not understand the details of their Medicare benefits and lack the information needed to supplement those benefits.

Utilitarianism would provide a very different analysis of the use of life-sustaining technologies during terminal illness. It would ask what the benefits are in comparison to the costs (economic and social) and compare the net benefits from the use of these technologies with the net benefits of other uses of the resources.

Given that some people consider some uses of life-sustaining technologies during terminal illness a net loss, the case for their use will be a difficult one to make. The calculation will have to involve benefits to the patient as well as benefits to society. In both cases the benefits are problematic. Surely in some cases the patient benefits, either because the treatments relieve pain and suffering or because continued living is desired by the patient and/or others. Even in those cases, however, the benefits are likely to be small in comparison to the use of the resources in other ways.

In previous paragraphs, a distinction was made between persons who are inevitably dying and those who will die if they are not treated with a life-sustaining technology, but could probably live if treated. A distinction was also made between life-sustaining technologies that are used once to meet acute needs and those that must be used on a continuing basis. For the utilitarian, who is especially concerned about anticipated benefit, whether the illness is reversible or irreversible and whether use of the technology is acute or chronic will be very important.

Utilitarian analysis would also require taking into account the net benefits to society of the use of these technologies as well as alternative uses of the funds. Their use might be supported on grounds of societal benefits in rare cases where the terminally ill elderly person could still make a substantial social contribution, but that is likely to be uncommon. When compared with the use of the resources in other ways, the societal benefits are likely to be small.

The societal benefit that a more sophisticated utilitarian is likely to identify is the benefit for family members who will get positive value out of having a loved one remain alive even a short time longer. In some cases, these benefits could be significant such as when a relative is traveling from out of town and desires to see the dying person one last time. A strict utilitarian would insist that these benefits be included in the calculation. These social benefits, however, are extremely subjective and hard to quantify. Moreover, their inclusion has some unsettling implications. An ill elderly person with no relatives or friends would have no claim based on these benefits. This could lead to policies of using life-sustaining technologies for the terminally ill only in cases where there are relatives. Extending the argument one step further, their use might be reserved for those cases where relatives will be made happy by the dying person's continued existence.

There is one final issue raised by a utilitarian calculation. Different life-sustaining technologies may have different subjective impacts on the population. In some cases the decision to prohibit their use is likely to be very distressing to the sensibilities of some of the population. In other cases, the decision not to use the technology may produce little distress at all. For example, the level of psychological distress at the decision not to provide basic nutrition and hydration is probably much greater than that of deciding not to implant an artificial heart in a person who will inevitably die without one.

How should a utilitarian respond to these different subjective feelings on the part of members of the society? Should they be considered as benefits and harms of the treatment decision? It seems odd to decide whether to provide nasogastric tube feeding on the basis of whether it makes other people uncomfortable if such feeding is not provided. Decisions about what treatments should be provided are not normally made by determining whether citizens would be upset by their lack of provision. A utilitarian approach to allocating life-sustaining technologies will have to determine whether these subjective benefits and harms of providing life-sustaining technologies are relevant or whether a more objective measure such as years of life added should be used instead.

Maximin theorists and egalitarians would be much less concerned about whether the patient is terminally or critically ill and the frequency of treatment because aggregate benefit is not considered critical. Their major question is whether terminally ill elderly people constitute a least well off group or have the greatest needs and, if so, whether the technologies provide any benefit. Terminally ill elderly persons might well be considered a least well off group. From the slice-of-time perspective, they are in very bad shape. Yet from the over-a-lifetime perspective they are plausibly better off than persons who are terminally ill and young.

If terminally ill elderly people are viewed as a least well off group, they have claims to the resources that would benefit them. In the case where life-sustaining treatment is perceived as beneficial, maximin and egalitarian theorists who conclude that the terminally ill elderly are a least well off group would support treatment even if the benefits were minor.

There is room for dispute among these theorists when there is good reason to believe that the treatment would not be beneficial. What should happen, for example, when a dying elderly patient insists that an antibiotic be used for an infection and the consensus of medical opinion is that the antibiotic is extremely unlikely to overcome the infection and is very likely to produce undesirable side effects? Withholding the antibiotic is likely to produce distress for the patient, but supplying it is likely to produce harmful side effects. Maximin and egalitarian analysts will need to decide whether their theories require providing subjective benefit from the patient's perspective or only benefits measured in some more objective manner.

If terminally ill elderly people are viewed as a group that is not least well off, a different set of issues arises. Presumably maximin theorists and egalitarians would reach the conclusion that the life-sustaining technologies should be withheld on grounds of justice. Consider a dialysis patient who has a few days to live and those days will be lived in a state of semi-conscious stupor. It may be tragic to have to withhold dialysis or CPR from such a patient on resource allocation grounds, but if, by hypothesis, others are in greater need, then that is the decision a maximin theorist or egalitarian would support.

For life-sustaining technologies that also provide comfort and do so relatively inexpensively, the problem is more complex if terminally ill elderly people are not considered a least well off group. Consider a terminally ill elderly patient whose life will be sustained through hydration and nasogastric tube feeding. What should happen if withdrawing those treatments produces discomfort for the patient?

The egalitarian or maximin approach is that, if these are not least well off patients, they have no claim to the resource even if the suffering prevented is quite great and the cost of the treatment is quite small. For a terminally ill elderly person who has previously had a good life, the burden would probably have to be severe to outweigh the lifetime of well being. And finally, for another terminally ill patient who needs nutritional support for comfort, but who has had a miserable existence throughout his life, his claim for benefit would be much greater. For these reasons, some egalitarians argue that for providing the basics of comfort care, the slice-of-time perspective must be used but decisions pertaining to research, development, and experimental and high-technology treatment require an over-a-lifetime perspective.

Consideration of Age as a Criterion in the Allocation of Technological Resources

Many criteria are relevant to decisions about the allocation of technological resources. First, it is possible to distribute resources according to each theory of justice or some combination thereof. The health care delivery system in the United States, for instance, is based on an amalgam of competing points of view about what is fair and equitable. Second, it is possible to distribute resources in a discriminating way in terms of kinds of care (e.g., prevention, diagnosis, treatment, and rehabilitation), relative costs, merit, need, or age group. Because this report focuses on the use of life-sustaining technologies and elderly people, a discussion of the ethical implications of the use of age as a criterion for the distribution of resources is particularly relevant.

Age as a Direct and Indirect Measure

It is important to distinguish between two possible ways of using chronological age as a criterion in the allocation of technological resources. Age can be used in a direct way as the basis for allocating resources or, more commonly and probably more plausibly, age can be used as an indirect measure of some other variable that is thought to be the legitimate basis for allocating resources. Age can be an indirect measure of many different variables but the most obvious is as a predictor of medical benefit.

It has been common to use age as a basis for excluding patients from some procedures such as heart transplants. Both very old and very young patients were believed to be poor medical risks. Exclusion from dialysis on the basis of age was largely due to the belief that dialysis would not work well for older patients. This is of course an empirical argument that needs to be based on evidence about whether age really correlates with expected outcomes. (Note that exclusion from dialysis based on chronological age is *not* a practice under the current Medicare End Stage Renal Disease Program.)

The medical benefit criterion is attractive because it appears to be objective but in reality, it often is not. The reasoning is that, if two people are candidates for an organ transplant and one will live more years than the other, then the person who will live longer becomes the correct recipient of care. That may well be the case, but if it is, it is not without evaluative judgment. The notion of medical benefit often includes not only years of survival but the likelihood of complications, the amount of effort necessary to make the procedure successful, the likelihood of success, and many other factors. The complex combination of these that leads to the conclusion that one patient can benefit more than another is highly subjective.

Age can be an indirect measure not only of expected medical benefit, but of a number of other factors that are significant in various theories of justice. The most obvious is that age is an imperfect predictor of years of life potentially added by a life-sustaining intervention. This is true especially for acute interventions such as antibiotics. *Other things being equal*, a 70-year-old person can be expected to gain more years of life from an antibiotic for pneumonia than an 80-year-old person. If the policy were to allocate to the person who would get the most life-years from the treatment, then age would be an important factor in deciding who gets treatment.

In addition, age is an inadequate measure of the amount of well-being or quality of life one has had over a lifetime. For those who work with an over-a-lifetime concept of equality, age is an important predictor of how much well-being has been accumulated, other things being equal. The problem, of course, is that other things are not usually equal. Age is a predictor of medical success, years of life potentially added, or cumulated well being, but it is an imperfect predictor. So even if one accepts age as a legitimate basis for allocating technologies, it does not follow that chronological age can be used as the sole basis for allocation.

Arguments in Support of the Use of Age as a Criterion

At least four ethical arguments can be employed to defend the use of age as a criterion in allocating health care resources. They are: 1) the "age demands respect" argument; 2) the "age as a predictor of accrued benefit" argument; 3) the "over-a-lifetime well-being" argument; and 4) the argument from contract.

The "Age Demands Respect" Argument.—It is striking that in traditional societies age was without question a legitimate basis for allocating certain resources. The elderly commanded a special place as people deserving respect. Some vestiges of this remain in our society. Older persons are still occasionally given courtesies of title. They still sometimes expect higher salaries for work similar to that done by a younger person. These practices reflect the conviction that age brings wisdom. Even in an era of orientation to youth, it is important to realize that using age as a criterion of allocation does not necessarily mean that elderly people will be less likely to receive life-sustaining technologies. For instance, if there were a choice between a 65-year-old and a newborn infant, some people might opt for the elderly person on the grounds that a person whose character is fully developed demands respect over an infant.

The "Age as a Predictor of Accrued Benefit" Argument.—A second argument for the use of age as a criterion is more likely to lead to decisions limiting access to life-sustaining technologies. This argument uses age as a predictor of the benefit that will accrue from intervention. The benefit includes the medical factors considered above, but also, especially for one-time interventions, the years of life added, the useful contribution of the individual to the society in the future, and other factors.

Utilitarians would defend the use of age even if it is only an imperfect predictor of utility. The utilitarian, driven to maximize net benefit, would concede that it would be best to use life-sustaining resources in the way that maximizes their benefit. They would concede that occasionally older people get great benefit out of life-sustaining technologies and that they might continue to live and contribute to society if such technologies were used. They also concede that some younger people ought to be disqualified if usefulness to the patient and to society were the criteria. They might argue, however, that there would be great disutility in setting up complex procedures for determining which elderly persons of a particular age were the exceptions that justified special consideration. The labor and psychological stresses involved might make it such that the most efficient way to maximize utility is simply to include or exclude all persons of a particular age, ignoring the fact that some persons would thereby be wrongly classified.

The Argument for Over-a-Lifetime Well-Being.—A third argument for the use of age as a criterion leads to a similar conclusion—limiting access to life-sustaining technologies—but on very different grounds. This argument works from the maximin or egalitarian theory of justice and uses the over-a-lifetime perspective for determining who is least well off. However, attempting to assess individual variations in lifetime well-being for two persons of similar age would be an overwhelmingly complicated task. For policy purposes, so the defenders of this argument would claim, it is better to have a crude, simple basis for decisionmaking that will provide at least an approximation of cumulated well-being.

If this position is adopted, the older a person is, the less claim he or she has to resources. Diseases of infancy would appear to get very high priority, then diseases of children, etc. Those who have lived to old age would perhaps have a claim to the basics of care—safe, simple treatments of basic problems, comfort care, and standard medicine, but not expensive, high technology or experimental treatments. Instead of delivering these complex, expensive treatments to the elderly, more work should be done for those who otherwise will never have the opportunity to see old age.

The Argument From Contract.—A final argument can be offered that may lead to the conclusion that age can legitimately be a criterion for allocating health care (15). It draws on certain egalitarian premises, but also incorporates many of the ideas of those committed to individual liberty. This approach struggles with the problem of what constitutes a fair transfer of resources for health care from the younger generation, who have the ability to pay for care, to the older generation, who have great need for care. It helps to think of the problem as more of an intrapersonal problem rather than an interpersonal one. Then the issue becomes one of how much of the resources available to the younger generation would prudently be saved for health care in old age.

This view argues that rational persons would allocate funds in a manner that does not necessarily provide the same health care services at all ages during their lives. Individuals in the population have a range of opportunities that vary from one age to another. What is normal functioning for one age is not for another. Prudence would dictate that persons would allocate their health care dollars with an eye to those "age relativized opportunity ranges" (15). The result would be different patterns of health care for different age groups, but comparable levels of satisfaction for individuals. "Justice requires that we allocate health care in a manner that assures individuals a fair chance at enjoying the normal opportunity range, and prudence suggests that it is equally important to protect an individual's opportunity range for each stage of life" (15).

The over-a-lifetime perspective seems to imply that the younger a person is, the greater the claim to societal resources. As a practical policy matter this perspective could create some serious problems—say of choosing between a 33- and a 34-year-old person on the basis of age. Since the primary area of controversy is over the use of expensive, marginally beneficial resources for those who have met many of their life goals, it is possible that some cut off point would be adopted in using age as a criterion. Here use might be made of the newer distinctions among subgroups of elderly people. It is possible that an age criterion could be used for limiting certain life-sustaining technologies only for the older subgroups. It is also possible that if age criteria are generally adopted, different age ranges would be adopted for different subgroups of elderly people.

Arguments Against the Use of Age as a Criterion

The arguments favoring the use of age as a criterion for allocating health care resources clearly depend on which theory of justice one adopts. The counterarguments will also follow the patterns established in the theories of justice debate. Any argument against the premises of the particular theory of justice will turn out to be a reason to oppose the use of age as a criterion. For example, anyone who rejects utilitarianism will likewise reject the utilitarian reasons why age might be used as a criterion.

Egalitarianism With the Slice-of-Time Perspective.—Perhaps the most common argument on both sides of the debate over the use of age as a criterion in allocating resources is the argument that people should be treated equally and that that means equal needs should have an equal chance of being met regardless of age. In other words, people equally sick at a given point in time have an equal claim.

Libertarianism.—An argument against the use of age as a criterion for allocating life-sustaining technologies is rooted in the libertarian theory of distribution. It emphasizes that life-sustaining technologies, like other goods and services, should be available to those who want to purchase them or to those who are the recipients of gifts or exchanges from others who control these services. Under this view, anyone who has the resources (either direct funds or insurance coverage) should have access regardless of age.

Age might enter into individual choices about whether to make use of life-sustaining technologies for instance, some elderly people might reason that they would rather have their resources used for other purposes. Age might also influence the distribution of resources, thereby determining who has the funds to purchase life-sustaining technologies. But age per se would not, according to the libertarian perspective, determine who should have access to any resource including life-sustaining technologies. If some people are unable to gain access because of lack of resources that is unfortunate, but not unfair.

The Utility Arguments About Using Age as a Criterion.—Utilitarians would argue that since age is an indirect indicator of other factors that correlate highly with the amount of benefit produced by life-sustaining technologies—factors such as predicted medical success, years of life added, and social usefulness of the life saved—it is most efficient to operate under some general rules that allocate life-sustaining technologies strictly on the basis of age.

Other utilitarians might push this reasoning one step further. They might be concerned about the disutilities of having some persons in the society receive life-sustaining technologies while others—equally sick and equally at risk—do not. They might argue that to minimize the social friction created by age cutoffs, everyone, regardless of age, should have the same access to life-sustaining technologies. That rule, even with the inefficiencies that result from delivering care to elderly persons who are likely to gain very little benefit and add very little to society, may end up producing more good than trying to institutionalize age-based discrimination.

The Life-is-Sacred Argument.—Still another argument against the use of age as a criterion is specific to life-sustaining technologies. Some people in certain religious and cultural traditions believe that life in all of its moments is sacred. They hold that life should never be shortened by the withdrawal or withholding of medical technologies under any circumstances. They consistently oppose withholding mechanical ventilators, the writing of DNR orders, and the refusal of any other life-sustaining treatments such as nutritional support and antibiotics. Anyone taking this position would necessarily oppose the use of age as a criterion for determining who should get life-sustaining technologies.

The Use-of-Sociological Categories Argument.—A final argument against the use of age as a criterion draws on parallel debates from the civil rights and women's rights movements. In the early phases of these debates, some who would defend discrimination on the basis of age or sex did so using the argument that sociological categories (e.g., race or sex) can be used to predict performance or success in the workplace and other settings. This generated substantial argument. Members of minority groups took strong exception. They argued that it was unfair to assume that they, as individuals, would perform poorly, that they would follow the stereotypes of a particular sociological group.

The critics of the use of ascribed sociological categories have now largely won the debates regarding sex and race. These factors now can legally be used as selection criteria only in very special circumstances where sex or race are inherently linked to a job.

The implications for the use of age as a selection criterion are apparent. Age, as has been indicated, is almost always used as an indirect, imperfect indicator for some other factor thought to be relevant in selection. Furthermore, chronological age is an ascribed category. There is nothing anyone can do by hard work to change it anymore than one can (with very special exceptions) change race or sex. If race and sex cannot be used for allocation without being unfair, does it not follow, so these critics argue, that age likewise cannot be used? This leads to the conclusion that anyone who wants to exclude a particular patient on the basis of medical benefit, utility calculations, or accumulated well being over a lifetime would need to find direct evidence that these factors justify exclusion in the particular patient. Age per se could not be used as a sociological short cut to these factors.

Mixed Arguments Regarding Age as a Criterion

It is possible to accept the use of age as a criterion in certain circumstances and reject it in others. Some egalitarians are experimenting with a differentiated approach whereby age is legitimately used in allocating research and development funds, experimental treatments, expensive treatments, and those with low likelihood of success while everyone would have equal access on the basis of need to inexpensive, safe, and effective treatments and to comfort care regardless of age. Other formulas for mixed policies where age is sometimes used as a criterion and other times is not are likely to emerge in the future.

Intergenerational Responsibilities and Conflicts

Considering the use of age as a criterion for allocating life-sustaining technologies poses the problem of intergenerational responsibility and conflict among generations. Thinking of the use of life-sustaining technologies for the terminally ill elderly, many elderly individuals have come to the conclusion that such uses, even if they are desired, consume large amounts of personal resources that could better be used by one's children and grandchildren. On that basis, some individuals wish to forgo the use of life-sustaining technologies during life-threatening illness. If individuals make such decisions with their own resources, the question arises whether at the public policy level decisions should be made such that society's resources are not used excessively for the older generation.

If many people consider the benefits of using their resources for life-sustaining technologies small or even nonexistent, the utilitarian perspective would reasonably support preservation of the resources for future generations. In fact, it is not clear that this preservation of resources would be limited to existing generations. The calculation of benefits and harms could include all future persons, whether presently living or not. However, some people have argued that those more than two or three generations in the future will be so different from us that it will be virtually impossible to predict their interests and that, therefore, they do not need to be taken into account (18). Others are not as convinced of the radical discontinuity between our generation and future ones (9). At least when it comes to the desire of future generations to avoid end-stage kidney disease, infections, dehydration, nutritional deficit, and sudden cardiac or respiratory arrest, it seems reasonable that those in the future are likely to want these problems solved.

Similar problems of intergenerational responsibility arise for maximin theorists and egalitarians. They must determine whether the present terminally ill elderly are among the worst off groups, taking into account the existing younger generation and possibly future generations as well. In fact, some ethicists and economists have worried a great deal about justice between generations (34). Because no one knows into which generation he will be born, the result will be what is called the "just savings principle" where there is "an understanding between generations to carry their fair share of the burden of realizing and preserving a just society" (34).

The intergenerational responsibility problem is critical for what is called the prudent saver model of resource allocation (15). Health coverage for the elderly is essentially a scheme whereby each older generation is the beneficiary of the resources of the younger generation. If a plan providing age-relativized opportunities for health care is once in place, even if elderly persons did not get the same levels of coverage for life-sustaining technologies, everyone would be treated fairly—at least if every generation were of the same size and contributed equally. The intergenerational transfers would theoretically cancel out with each younger generation contributing to the support of the older generation.

However, all generations may not be equally equipped to pay for care of the elderly. Some paying generations may be quite small yet have to pay for care for an elderly generation that is large. Other generations may face the opposite demographics. Some generations may face long periods where economic conditions make it difficult to pay for care for the older generation. From the point of view of a distribution system emphasizing equality, adjustments would need to be made to even out the ratio of burdens to benefits. In any case, if a plan using age as a criterion for allocating life-sustaining technologies were suddenly institutionalized, adjustments would have to be made to deal with intergenerational responsibilities during the transition generations and between generations that had unequal abilities to support health care.

One of the key problems of intergenerational responsibility is the extent to which children bear responsibility for their parents in a direct way. Both recognize that the parental generation transfers resources to the younger generation during early years and that some reciprocal responsibility is borne by children for their parents during their old age. At the same time, both place substantial limits on the obligation of the younger generation for the older. Some thinkers express this in terms of the obligation of each generation to save for its immediate descendants (34). Others look at it in terms of the way a prudent saver would allocate a life's resources (15). In both cases, it is clear that limits exist on what would be transferred from the younger generation to the older. Taking a somewhat different perspective, government programs to meet the needs of the elderly can be seen as a way of easing tensions between generations: the younger generation would not bear a responsibility for providing care for the older, but would nevertheless remain in contact with them through family ties.

Photo credit: Foster Medical Corp.

Intergenerational needs and life-sustaining technology.

FINDINGS AND IMPLICATIONS

The ethical issues associated with the use of the five identified life-sustaining technologies on behalf of life-threatened elderly individuals are many and varied. This chapter is just a sampling of significant ethical arguments and does not treat all of the relevant ethical issues. Nonetheless, important findings emerge:

- Categorical distinctions can be helpful in clarifying the specific points at which ethical dilemmas exist but do not lend themselves readily to clear criteria for decisionmaking.
- According to several ethical traditions, the relevant considerations in decisionmaking are the patient's wishes and interests, in light of his or her condition; societal allocation of resources; and the necessity for some societal rules, such as the prohibition of killing.
- Each of the life-sustaining technologies discussed in this assessment raises a heterogeneous, though not necessarily a unique, combination of ethical issues and questions.
- There is insufficient data from which to draw any conclusions about a possible relationship between suicide among the elderly and the use of life-sustaining technologies.
- Whether or not an individual act of withdrawing a life-sustaining technology constitutes suicide or assisted death depends directly on how these terms are defined.
- The way in which health care services should be distributed to elderly persons depends directly on the theory (or theories) of justice that one holds and that can be effectively translated into public policies.
- The way in which life-sustaining technologies should be distributed to terminally ill elderly persons will depend in part on whether age is adopted as an appropriate criterion for allocation and on the availability of a particular technology.
- There are important arguments, both pro and con, for using chronological age as a criterion in the allocation of technological resources.
- An important factor in the alternative arguments about the use of chronological age in the allocation of resources is whether one adopts an "over-a-lifetime" or "slice-of-time" perspective concerning individual quality of life and human welfare.

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Chapter 5

Resuscitation

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Chapter 5

Resuscitation

INTRODUCTION

In a person whose heart is healthy, the functioning of the heart is intricately timed and orchestrated to supply the brain, lungs, body tissues, and organs with blood. When a person's heart stops beating, or beats so ineffectively that blood circulation is not sufficient to supply the brain with oxygen and nutrients, the brain is irreversibly damaged within minutes, spontaneous breathing cannot be recovered, and death ensues quickly. Cardiopulmonary resuscitation (CPR) offers a way to reverse the imminent threat to life.

Developed only 25 years ago, CPR is a widely applicable means of restoring and maintaining blood circulation and breathing in a person who has experienced a cardiac arrest. Basic CPR, that is, external cardiac massage and mouth-to-mouth ventilation, is familiar to most Americans, and many people have been trained to perform it. Advanced resuscitative techniques, such as the use of drugs and electrical shock to the heart, are less familiar to most people and are almost always performed by trained professionals.

CPR can be applied to anyone whose heart stops beating. Hence, all of the roughly 2 million people who die in the United States each year—70 percent of whom are elderly—are potential recipients. Because the alternative for a patient in cardiac arrest is death, ensuring access to CPR for all who need it is a vital public concern. Government agencies and nonprofit organizations, such as the American Red Cross and the American Heart Association, have developed large-scale educational programs to teach the basics of CPR to laypersons in local communities. Nevertheless, some elderly and other people who might benefit from CPR do not receive it. There are concerns that elderly people may be less likely than younger people to receive CPR because of a widespread perception that elderly people are less likely to benefit from it.

Somewhat paradoxically, given concerns about the underuse of CPR, many observers are also concerned about the possible overuse of CPR. Poor long-term survival rates, the risk of injuries and complications associated with the procedures, and the possibility of survival with severe physical and neurological impairment have prompted some observers to question the appropriateness of this technology for certain patients, especially those who are terminally ill and severely debilitated.

Because of the suddenness of cardiac arrest and the urgency of initiating treatment quickly if at all, decisions about CPR must be made momentarily after the arrest or at some time before an arrest occurs. In the community, cardiac arrest is usually unexpected. Paramedics, emergency medical technicians, and trained laypersons who perform CPR in this setting often know nothing of the patient's background and are not qualified to assess the patient's medical condition. In the community, therefore, the presumption is generally that efforts to resuscitate victims of a cardiac or respiratory arrest should be initiated automatically, as quickly as possible, and continued until effective spontaneous circulation and breathing are restored, the patient is transferred to a hospital, or the rescuer is exhausted and unable to continue.

CPR is also usually initiated automatically in hospitals. For some patients, however, the possibility of cardiac arrest is anticipated, and a decision about whether to administer CPR is reached in advance. For some of these patients, a decision is made to withhold CPR.

There are many problems in arriving at and implementing decisions to withhold CPR. In some cases, physicians, nurses, and other caregivers disagree about whether a particular patient should be resuscitated. Many physicians do not discuss decisions about resuscitation or the possibility of a Do-Not-Resuscitate (DNR) order with their patients (5). DNR orders are sometimes inadequately documented or not documented at all in the patient's medical chart. Some health care facilities do not allow physicians to write DNR orders, and some physicians avoid writing such orders for fear of legal liability (43,90).

These problems have prompted many observers to encourage adoption of clearly formulated institutional policies to define procedures for making decisions about resuscitation (14,69,71). In response, the Joint Commission on Accreditation of Hospitals (JCAH) has developed a standard that will require hospitals and nursing homes to have a formal policy about how such decisions should be made in order to be accredited by JCAH (67).

This chapter discusses resuscitation techniques, their use for elderly patients, and the processes by which decisions about CPR are made. CPR includes a range of techniques that vary in their technological sophistication and invasiveness. Since decisions about resuscitation also involve decisions about which of these techniques should be used, the chapter includes some information about the various techniques.

DESCRIPTION OF RESUSCITATION

Cardiac Arrest: The Need for Resuscitation

People need resuscitation as a result of either cardiac or respiratory arrest. Cardiac arrest is the sudden unexpected cessation of heartbeat and blood pressure. It leads to loss of consciousness within seconds, irreversible brain damage in as little as 3 minutes, and death within 4 to 15 minutes (14,87).

Respiratory arrest is the sudden cessation of effective breathing (see ch. 6). Without effective breathing, the blood is unable to supply adequate oxygen to the heart and brain or eliminate carbon dioxide from body tissues. Consequently, respiratory arrest will be followed within minutes by gradual loss of consciousness and then by cardiac arrest. Ascertaining whether a cardiac arrest was caused by a respiratory arrest is often impossible, and virtually all cardiac arrests are accompanied within minutes by cessation of breathing (14).

Although the majority of people who suffer cardiac arrest are elderly, the nature and underlying causes of their arrest vary widely. Cardiac arrest frequently results from a myocardial infarction (loss of blood supply to the heart, commonly known as a heart attack), but can result from a variety of other conditions, including kidney failure, hemorrhage, and metabolic disorders. The frequencies of various causes of cardiac arrest cannot be precisely ascertained, because the underlying medical conditions that result in arrest are often not known or not reported, and an autopsy is usually not performed (13).

In the vast majority of patients, cardiac arrest is the end point in the course of coronary artery disease. Atherosclerosis—the accumulation of fatty substances and growth of fibrous coronary tissue in the walls of arteries underlies most coronary artery disease and is a distinctly age-related disorder.

Many patients who experience cardiac arrest also have other physiological problems that contribute to their arrest by placing strain on the heart. The most common problems are renal failure, diabetes, pneumonia, and cancer—conditions that are more prevalent among elderly than younger people (6).

Any one of various heart disturbances—arrhythmias, asystole, or electromechanical dissociation—may precede or initiate cardiac arrest. The most serious of the cardiac arrhythmias (abnormal heartbeats) is ventricular fibrillation, in which the ventricles of the heart twitch or beat in an uncoordinated pattern without effective contraction and cardiac output. Ventricular fibrillation occurs in approximately 60 to 90 percent of cardiac arrests taking place in the community and in 33 to 40 percent of those taking place in the hospital (14). It is also the most frequent cause of death prior to hospital admission (66). Other arrhythmias associated with cardiac arrest are ventricular tachycardia, which is characterized by rapid regular or only slightly irregular beats; and bradycardia, or abnormally slow heartbeats.

Asystole (the absence of electrical activity in the heart) and electromechanical dissociation (the failure of a normal electrical impulse to cause contraction of the heart) cause a smaller proportion of cardiac arrests than arrhythmias (26). Arrhythmias, asystole, and electromechanical dissociation can be diagnosed with the aid of an electrocardiograph (EKG) machine, that measures the electrical activity of the heart and graphically depicts the heartbeat by a series of waves.

History of Resuscitation

Attempts to resuscitate people with cardiac or respiratory arrest began almost as early as recorded history. Modern closed-chest cardiac massage, however, was not developed until 1960, when W.B. Kouwenhoven and his associates first applied it (45). Prior to that time, cardiac arrest was sometimes treated by surgically opening the patient's chest and directly massaging the heart. With the method developed in 1960, however, a rescuer rhythmically applies pressure to the patient's sternum (breastbone); this pressure compresses the heart and restores circulation without opening the patient's chest.

Successful application of closed-chest cardiac massage and the increased technological capability to monitor heart rhythm and to safely apply electrical shock all contributed to the rapid and widespread acceptance of CPR in hospitals during the 1960s and shortly thereafter by emergency rescue teams.

It was soon discovered that the outcome of CPR depended largely on how quickly it was initiated. In many cases where people collapsed outside a hospital, brain damage or death occurred before an ambulance arrived. In an attempt to minimize this time lag and to bring the ability to resuscitate out of the hospital and into the community, public agencies and nonprofit organizations developed programs to teach the basics of CPR to community laypersons, high school students, and others (14).

Procedures Involved in Resuscitation

Many people think of resuscitation as it is portrayed on television—a bystander, a paramedic, or an emergency room physician pumping on a person's chest until the person either dies or is revived. In fact, however, resuscitation consists of a wide array of procedures, often involving sophisticated and specialized techniques and equipment.

> It was a Thursday morning, rounds were done, and the intern and medical student sat down for a quick breakfast. Suddenly, from overhead, "Code blue . . . Code blue . . . Code blue . . . Code blue . . .!" They leapt up and ran.
>
> . . . When they arrived, resuscitation was already in progress. Another medical student was rhythmically pushing on Mr. H's chest, and having difficulty with the position, climbed onto the bed to continue. A large cart loaded with drugs was near the door to the room, manned by two nurses. Another nurse was giving him oxygen with a mask and a bag, and an anesthesiologist was standing by, ready to put a breathing tube in Mr. H's trachea. The intern periodically drew blood from the groin and a medical student ran the blood samples to the lab to measure oxygen and acid.
>
> . . . Above the confused chatter, shouts of "atropine!", "more bicarb!", "epinephrine!", and other names of drugs could be heard from the resident who took charge of the code. The EKG machine spewed out yards of paper strips showing no heart beat. The resident took the defibrillator paddles several times, applied them to the reddened, raw chest, shouted "All clear!", and everyone momentarily moved back. The lifeless body jerked with each shock (14).

In describing the spectrum of procedures involved in resuscitation, it is helpful to divide the process into two stages: basic and advanced life support. Basic life support is administered to a person in cardiac arrest by a "rescuer," either a trained bystander, an emergency medical technician, a paramedic, a nurse (especially if initiated in a hospital), or any other health professional. Advanced cardiac life support includes basic cardiac life support and other specialized equipment and techniques and is administered by paramedics or other medical personnel. In the hospital, advanced cardiac life support is usually initiated by nurses and continued within minutes by a team of physicians.

Basic Life Support

Basic life support consists of what are referred to as the ABCs of resuscitation: Airway, Breathing, and Circulation (see fig. 5-1).[1] When a rescuer arrives at the scene of a collapsed victim, he or she determines that the person is unresponsive and immediately calls for help. After positioning the victim and ensuring that the victim's airway is open, the rescuer determines whether he or she is breathing by looking for chest movement and listening and feeling over the mouth for airflow.

If no breath is detected, the rescuer performs mouth-to-mouth ventilation. This involves blowing air into the victim's mouth and determining whether the victim's lungs are being ventilated by watching for chest movement and hearing or feeling the air escape during exhalation.

If a carotid pulse at the victim's neck is absent, the rescuer begins external chest compressions. Rhythmic compressions of the sternum provide circulation to the heart, lung, brain, and other organs. Blood circulated to the lungs by external chest compressions will receive enough oxygen to maintain life when accompanied by properly performed mouth-to-mouth ventilation (64).

Advanced Cardiac Life Support

Advanced cardiac life support consists of basic life support and the techniques and machinery that sustain life after the immediate, manual steps are taken. It frequently involves the use of special equipment and procedures for establishing an airway and maintaining effective ventilation and circulation.

Depending on the setting, condition of the victim, and skill of the available personnel, an airway device may be inserted through the victim's nose or mouth into the throat to keep open a path for air behind the tongue (see fig. 5-2). The airway of an unconscious victim is most effectively secured with an endotracheal tube (a tube inserted through a person's nose or mouth into the trachea). An endotracheal tube can protect the patient's esophagus during artificial ventilation (14).

To maintain ventilation, a bag-valve unit (a mask attached to a bag) can be used to deliver either room air (when the mask is placed over the mouth and nose and the bag is squeezed) or oxygen (when a source of supplemental oxygen source is attached to the bag-valve device). A bag-valve unit or a mechanical ventilator can be attached to an esophageal obturator airway (see fig. 5-2), or an endotracheal tube. The efficacy of ventilation is determined by monitoring the patient's pulse, pupil reaction and size, and spontaneous respirations, and by periodically testing the blood for oxygen and carbon dioxide levels.

Supplemental oxygen is used as soon as it becomes available. This is necessary to correct low levels of oxygen in a patient's bloodstream.

Several devices can help to maintain circulation. A cardiac arrest board, placed under the patient's back, provides a firm surface to aid in compression of the chest and heart. Gas- or oxygen-powered mechanical devices for external chest compression may be used to allow consistency in the depth and length of compressions. These devices are found in some emergency rooms and intensive care units (ICUs) and may be used in addition to manual chest compression for cases where prolonged resuscitative efforts are necessary.

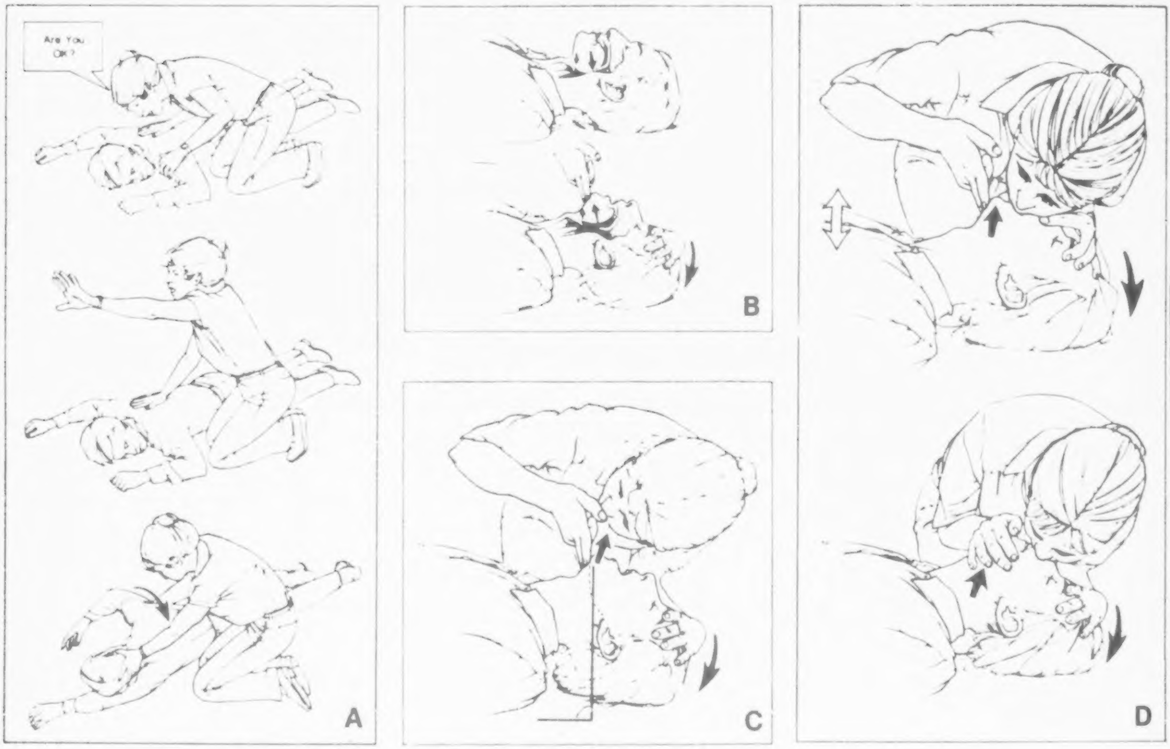
An electrical defibrillator is used to convert ventricular fibrillation to a normal heart rhythm. A defibrillator produces a high-voltage current averaging 4,000 volts, which is delivered over 4 to 12 milliseconds via two paddles placed externally on the patient's chest, on either side of the heart. When left in place, the paddles can also detect the patient's heart rhythm and display it on a monitor (14). An electrical defibrillator can also be used to convert ventricular tachycardia to a normal heart rhythm, a process called cardioversion. Like defibrillation, cardioversion involves a brief electrical shock to the heart, delivered through two paddle electrodes placed on the patient's chest; cardioversion differs from defibrillation in that it is timed to the heart's electrical activity.

In adult patients who experience cardiac arrest while being monitored, a precordial thump (a sharp, quick, blow administered over the midportion of the sternum within the first minute after cardiac arrest) may be effective in converting ventricular fibrillation or ventricular tachycardia to a normal rhythm. Recent studies indicate that precordial thump should not be used

---

[1] Although ABC stands for Airway, Breathing, and Circulation, the American Heart Association agreed in 1985 that ABC should stand for Assess, Breathe, and Circulate, as this was a more accurate description of what the rescuer must do (28).

Figure 5-1.—Administration of Basic Life Support


Are You OK?
A
B
C
D

A: Initial steps of cardiopulmonary resuscitation. Top, Determining unresponsiveness; center, calling for help; bottom, positioning the victim.

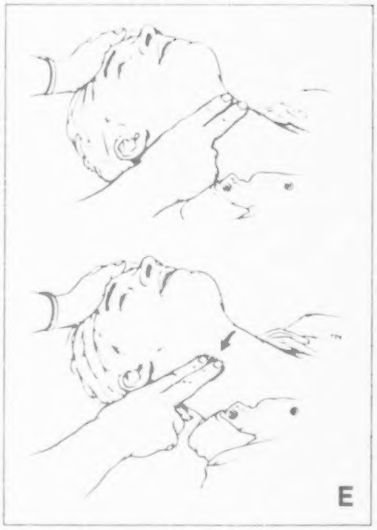
B: Opening the airway. Top, airway obstruction produced by tongue and epiglottis; bottom, relief by head-tilt/chin-lift.

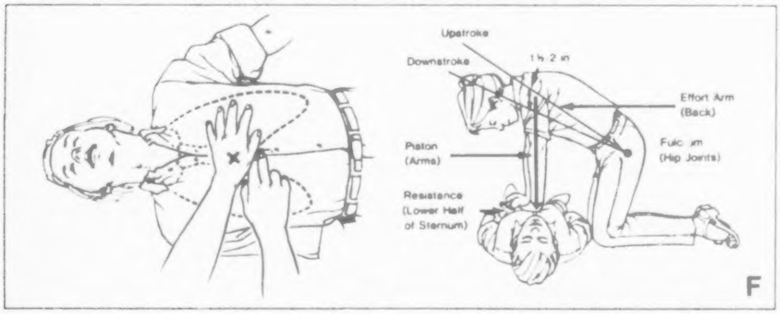
C: Determining breathlessness.

D: Rescue breathing. Top, mouth-to-mouth; bottom, mouth-to-nose.

E: Determining pulselessness.

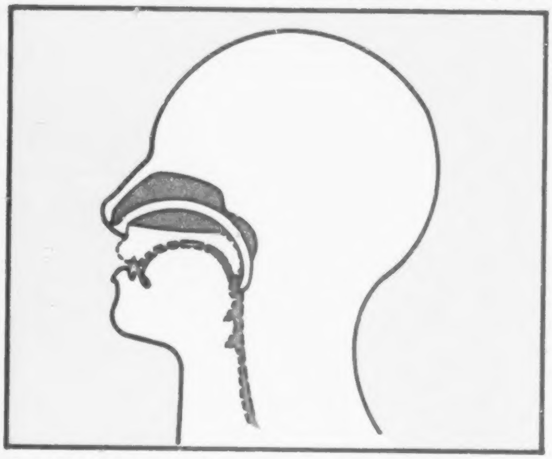
F: External chest compression. Left, locating the correct hand position on the lower half of the body; right, proper position of the rescuer with shoulders directly over the victim's sternum and elbows locked.



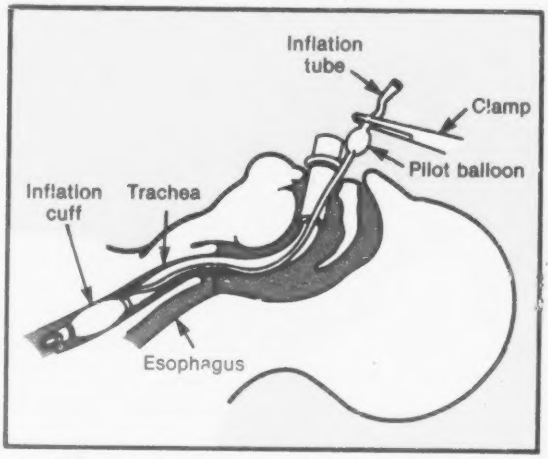

Upstroke
Downstroke
1½-2 in
Effort Arm (Back)
Piston (Arms)
Fulcrum (Hip Joints)
Resistance (Lower Half of Sternum)
F

SOURCE: National Conference on Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC), "Standards and Guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC)," *Journal of the American Medical Association* 255(21):2916-2920, 1986.

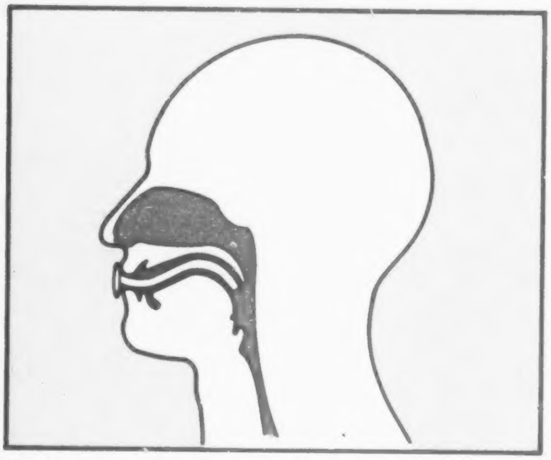
Figure 5-2.—Examples of Airway Devices Used in Advanced Cardiac Life Support



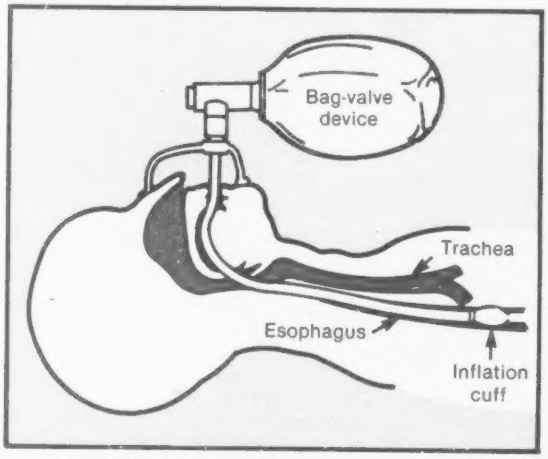
A nasopharyngeal airway may be inserted through the nose to the back of the throat to keep a path for air open.



An endotracheal tube with an inflatable cuff may be inserted through the nose or mouth (as pictured here) into the trachea. It is the most effective means of securing the airway of an unconscious patient.



An oropharyngeal airway may be inserted through the mouth to keep a path for air open.



An esophageal obdurator airway consists of a cuffed tube that is inserted through the mouth into the esophagus. Airholes in the portion that is in the throat allow passage of air into the trachea. A sealed mask prevents air leakage from the patient's mouth and nose. When the cuff in the esophagus is inflated, air is prevented from entering the stomach, stomach contents are prevented from entering the trachea and an open airway exists that can be used with a bag-valve device (shown) or a mechanical ventilator.

SOURCE: C.K. Cassel, M. Silverstein, J. La Puma, et al., "Cardiopulmonary Resuscitation in the Elderly," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1985.

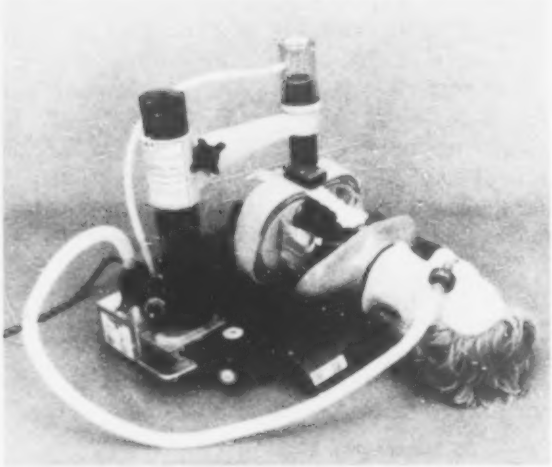


Photo credit: Hewlett Packard Co.

A mechanical device for external chest compression, demonstrated on a mannikin here, is sometimes used instead of manual chest compression, especially when prolonged resuscitative efforts are needed.

in out-of-hospital resuscitation because of the risk that it may thump the victim into a more malignant rhythm (13).

Drugs, administered either intravenously, by direct injections to the heart, or via endotracheal tube, play an essential role in advanced cardiac life support. Some drugs (e.g., sodium bicarbonate) can treat life-threatening accumulations of acid caused by lack of oxygen and retention of carbon dioxide. Many drugs (e.g., epinephrine and atropine) influence heart rate and contractility, as well as blood pressure. Some drugs (e.g., low doses of dopamine) dilate blood vessels, and others (e.g., methoxamine, phenylephrine, and high doses of dopamine) constrict them. Other drugs (e.g., lidocaine, procainamide, and bretyllium) can correct arrhythmias in some cases. Finally, some drugs can also make a patient with ventricular fibrillation more responsive to electrical shock (14).

Although not a common part of the resuscitation procedure itself, temporary cardiac pacing is sometimes used to regulate a patient's heart rhythm. Temporary pacemakers are ineffective for some heart rhythm disturbances and tend to be used late in resuscitation, after other therapies prove inadequate to establish stable circulation (22). There are three basic approaches to cardiac pacing during CPR: external, transthoracic, and transvenous. External pacing uses skin electrodes to pass repetitive electrical impulses through the chest wall, to electrically stimulate the heart. In transthoracic pacing, the physician inserts the pacing electrode through the patient's chest and into the heart muscle. In transvenous pacing, the physician inserts the pacing electrode through a large vein near the patient's collarbone and into the heart. In all three cases, the pacing electrode is connected to an external temporary pacemaker.

Photo credit: Hewlett Packard Co.

An electrical defibrillator can be used to deliver a shock to a patient's chest to restore normal heart rhythm.

Open-chest cardiac massage is the most drastic means of attempting to restore circulation. This procedure involves surgically opening the patient's chest and breaking the ribs so that the heart can be directly massaged. It is sometimes used for patients who fail to respond to standard, closed-chest methods of resuscitation. The American Heart Association currently recommends using open-chest cardiac massage for patients with penetrating chest injuries, severe hypothermia, cardiac tamponade (where the sac surrounding the heart fills with blood or fluid), or anatomical deformity that precludes closed-chest compression, and in patients who suffer a cardiac arrest in the operating room when their chest is already open (64).

An in-hospital resuscitation attempt may include one, all, or any combination of the various measures described above, applied once, repeatedly, or continuously. There is no theoretical limit to the number of times a patient can be resuscitated, although the chance of complications and injuries increases with every attempt. In a hospital, it is not uncommon for a patient with multiple cardiac arrests to be resuscitated repeatedly. A review of 13,266 hospital CPR cases reported in the medical literature from 1960 to 1980 found that 11 percent of CPR patients were resuscitated twice in one hospital stay; 2 percent were resuscitated three times; and about 1 percent were resuscitated four times (23). One terminally ill patient was reportedly resuscitated 70 times in a 24-hour period (2).

For patients who survive a cardiac arrest, recovery is rarely a simple matter of "waking up" after the resuscitation is completed. A patient's heart rhythm may continue to be abnormal and may require continuous monitoring, intravenous medication, or a pacemaker. A patient may also require continuous infusion of medicine to support his or her blood pressure and maintain effective blood flow (14).

Successfully resuscitated patients are critically ill due to serious underlying disease, cardiac arrest, and the risk of recurrent cardiac arrest. They typically require intensive medical care and are frequently admitted to the hospital's ICU or coronary care unit (CCU) (14).

When To Discontinue CPR

There is no theoretical limit on the duration of a resuscitation attempt. Resuscitation attempts may extend anywhere from a few minutes to hours, although they usually last 30 to 60 minutes (14). Patients whose hearts begin to beat spontaneously within 15 minutes are more likely to survive than patients requiring CPR for a longer time (6).

The 1980 American Heart Association Standards for Cardiopulmonary Resuscitation and Emergency Cardiac Care (ECC) state that CPR should be continued until a patient recovers or "is found to be unresuscitable and is pronounced dead." In general, death may be determined on the basis of: 1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all functions of the entire brain, including the brain stem, i.e., brain death (see ch. 2). Brain death cannot be determined before or during resuscitation, however, because 6 to 24 hours of observation are needed, along with more than one flatline EKG. Other indicators of brain death, such as lack of pupil response and reflexes, are unreliable—particularly in elderly patients, who may have unreactive pupils due to cataract surgery or who are taking medications that may affect neurological responses (64). Thus, according to experts, a decision to discontinue CPR should be based on a finding of irreversible cessation of cardiovascular function after basic and advanced life support have been properly applied (56,63,64).

Specific clinical criteria for when CPR should be discontinued have been proposed, but examples of the complete recovery of patients whose resuscitation would have been terminated under some of the proposed criteria can be cited (14). Some observers argue that no criteria would be appropriate in all cases and that the decision about when to discontinue CPR must be made on a case-by-case basis (16).

Special Considerations in the Use of CPR for Elderly Patients

The use of some resuscitative procedures for elderly patients may be complicated by age-associated illness or physiological changes. Arthritis of the vertebrae in the neck, a condition that is common in elderly people can create difficulty in some of the airway maneuvers. Rheumatoid arthritis, which frequently affects the joint where the jaw joins the skull, can interfere with CPR by making the mouth difficult to open fully. Moreover, age-associated illness or physiological changes may increase the risk of resuscitation-related injuries (see "Complications and Injuries Associated With CPR" below). These age-associated problems are not known to affect short- or long-term survival following CPR (14).

In comparison to younger people, elderly people tend to have less muscle mass, more fatty tissue, and reduced blood flow to the liver and kidneys (two main organs of drug elimination and metabolism). These age-related physiological changes may affect the way an elderly person's body absorbs, metabolizes, distributes, and eliminates drugs (see ch. 9). How the drugs used in resuscitation are affected by these changes is not known, although anecdotal evidence suggests that there may be increased variability in response among elderly patients. No guidelines exist for dosages of these drugs for elderly patients.

Other age-associated problems may impede monitoring an elderly patient's response to a resuscitation attempt. Many elderly people have stiffer arteries than younger people, making their pulse more difficult to detect (14). Furthermore, some elderly people take medications that affect their reflexes and other neurologic responses. Detecting symptoms or changes in neurological status in such individuals can be difficult.

Although age-associated factors may complicate resuscitative procedures for some elderly patients, impede monitoring of their response to treatment, and increase the risk of resuscitation-related injuries, there is no evidence that CPR is performed differently on elderly people than on younger people. Many of the procedures must be applied in full force in order for maximum benefit to be achieved. Thus, although a patient's age may affect the decision to resuscitate (see section below on "Making Decisions About Resuscitation"), once the decision to resusciate has been made, the procedures that are used are the same regardless of the patient's age, and little is done to reduce any additional risks associated with advanced age (13).

Treatment Settings

Most large hospitals have the necessary equipment and trained personnel for both basic and advanced cardiac life support. Some small hospitals do not have an ICU or CCU, and unstable resuscitated patients may be transferred by ambulance or helicopter to a larger facility (14).

In nursing homes, the specialized equipment and the personnel necessary for advanced cardiac life support are frequently not available. Most nursing homes do not have equipment for defibrillation. Thus, nursing home residents in cardiac arrest must be transferred to a hospital by ambulance after basic life support measures have been initiated. Some nursing home personnel are not even trained in basic CPR (14,41).

In the community, resuscitation is frequently performed by emergency medical technicians or paramedics attached to an ambulance rescue team. Even if basic CPR has been started by laypersons or medical personnel who happened to be present at the time of a cardiac arrest, it is often continued by an ambulance rescue team or occasionally a helicopter rescue team.

Emergency medical technicians and paramedics are trained in basic life support techniques. Since the 1970s, paramedics have also been trained to recognize various arrhythmias and use a defibrillator. Apart from the initial, standard treatment with external cardiac massage, intubation, intravenous line insertion, and defibrillation, however, all medications and treatment given by paramedics must be given on the orders of a physician based in an emergency room and in contact with the paramedics by radio (26).

CPR skills deteriorate rapidly if not practiced. With the exception of trained personnel who work in emergency rooms, ICUs, and CCUs, ambulance and helicopter rescue teams, and some interns and residents, few people use CPR often enough to maintain their skills. There are no data on how deterioration of CPR skills affects patient survival in any treatment setting (14).

UTILIZATION AND COST OF RESUSCITATION

Utilization of Resuscitation

For several reasons, accurate information on the utilization of CPR is difficult to obtain. Existing medical records systems do not necessarily code CPR. Thus, the progress notes made in the patient's chart by a nurse or physician are sometimes the only record of a resuscitation attempt, and these notes may be difficult to discern and quantify. No government or private agency keeps records of CPR attempts per se. Furthermore, reports of CPR administered in individual hospitals fail to provide information on the number of admissions per year or the number of bed-days

(days per year in which available hospital beds are occupied by a patient) associated with CPR (14).

Nursing homes seldom have comprehensive records of CPR attempts, because many nursing home residents who are resuscitated are transferred by ambulance to a hospital either before the arrest occurs or immediately after basic life support is initiated. Records of CPR attempts in the community are neither readily available nor necessarily comparable. Moreover, the records of emergency ambulance and helicopter rescue teams often do not include the number of people in the referral area, the number of ambulance calls, or the number of emergency room visits (14).

Several other problems limit the availability of accurate utilization data. In many reports, the patients receiving CPR are inadequately described, followup information is incomplete, and the population at risk for CPR or from which patients were obtained is not described or adequately reported. In addition, many reports of CPR include patients with trauma, hypothermia, or cold water drowning—groups of patients in whom the indications for CPR, utilization, and outcomes may differ from other groups. Elderly patients experiencing CPR may not be uniformly distributed in these groups (14).

As a result of these problems, there are no accurate figures on the number of persons who receive CPR in this country. Data from the 1984 National Hospital Discharge Survey, based on information from the medical records of a national sample of patients discharged from short-stay non-Federal hospitals, indicate that 120,000 persons of all ages received one or more of five specified CPR procedures[2]; about 73,000 (61 percent) of these persons were over age 65 (82). These numbers from the National Hospital Discharge Survey are much lower than estimates based on other sources on information, and they probably significantly underestimate the number of persons who receive CPR in hospitals.[3]

Data from other sources suggest that 370,000 to 750,000 or more persons of all ages may receive CPR in hospitals each year. One basis for this estimate is the observation that approximately 700,000 persons discharged from U.S. hospitals in 1984 had a diagnosis of acute myocardial infarction (81); although how many of these persons received CPR is unknown, it is likely that many of them did. Moreover, many patients with diagnoses other than myocardial infarction also receive CPR. In addition, data from several studies in individual hospitals suggest that 1 to 2 percent of patients in those hospitals received CPR (6,47). Applying this percentage to the approximately 37,200,000 patients discharged from short-term non-Federal hospitals in 1984 (81) yields a rough estimate that 372,000 to 744,000 patients may have received CPR in hospitals nationally.

The best available data suggest that cardiac arrest occurs in the community in 58 to 71 persons per 100,000 nationally (14). Yet, how many persons who experience cardiac arrest in the community receive CPR or how many are included in the hospital figures cited above is not known. No information about the number of persons who receive CPR in nursing homes or hospices is available.

Data compiled for OTA indicate that approximately 55 percent of hospitalized patients who receive CPR are elderly (14). Studies in some hospitals have found an even higher percentage of elderly persons among patients who received CPR. Of 294 patients who received CPR in a Boston hospital from 1981 to 1982, for example, only 20 percent were under 60 years old; 23 percent were

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[2] The five procedures are conversion of cardiac rhythm; cardiopulmonary resuscitation, not otherwise specified; other electric countershock of the heart; closed-chest cardiac massage; and open-chest cardiac massage (80).

[3] One reason the National Hospital Discharge Survey data may underestimate the number of people receiving CPR in hospitals is that the survey collects information on up to four medical procedures for each patient, and CPR may not be included as one of the four in some cases. This is especially likely since the survey form requests four "surgical and diagnostic procedures" (80). Moreover, CPR attempts may only be noted in the physician's or nurses' progress notes and thus not easily extracted in the survey process.

60 to 70; 34 percent were 70 to 80; and 23 percent were over 80 (6).

If an average of 55 percent of patients who receive CPR in hospitals are elderly, and 370,000 to 750,000 or more persons of all ages receive CPR in hospitals, then 204,000 to 413,000 or more elderly persons may receive CPR in hospitals. Although very rough, this range corresponds to other estimates based on the finding that CPR is performed in about one-third of all hospital deaths (14). In 1984, 689,000 elderly persons died in short-stay non-Federal hospitals (81); if CPR was performed in one-third of these hospitalizations (or about 230,000 cases) and if death occurs in 75 to 90 percent of hospital CPR attempts (as discussed below), then it can be estimated that 255,000 to 307,000 elderly patients received CPR in hospitals.

Studies of patients receiving CPR in the community indicate that their mean age is 62. Detailed age distributions are rarely reported (14), but it is likely that most of the patients receiving CPR in both settings are over age 65. More than 75 percent of patients resuscitated in the community and 70 percent of those for whom resuscitation is attempted in the hospital are men (14), probably because men are more susceptible to atherosclerosis than women.

Cost of Resuscitation

Costs associated with resuscitation include the direct costs of procedures, equipment, and staff for a resuscitation attempt in the community or hospital; the cost of intensive care following resuscitation; and the cost of hospitalization following intensive care.

Some studies have analyzed the cost of community CPR by comparing program costs of establishing and maintaining an emergency medical service with the number of lives saved. OTA is not aware of any studies that measure the direct cost of procedures, equipment, and staff for a community CPR attempt. It is likely that the costs vary greatly from program to program, depending on the range of procedures performed and equipment available, the proportion of volunteer to paid staff, and the size of the service area.

In-hospital CPR may include any of several combinations of procedures (intubation, ventilation, defibrillation, pacemaker insertion, laboratory tests, drugs), and the costs of particular resuscitation attempts vary, depending on which procedures are used, the duration of each procedure, the number and type of personnel involved, and the costs associated with each. OTA is not aware of any studies that have observed and measured these components during actual CPR and then ascertained their costs.

To determine the charges associated with in-hospital CPR, one would need to observe the event, record the components, determine from the hospital bill which of the components had, in fact, generated charges, and total these charges. OTA is not aware of any study that has done this.

Patients alive at the conclusion of a resuscitation attempt are in almost all cases cared for in an ICU or CCU. One published report examined the charges for 2,693 patients admitted to a medical ICU between 1977 and 1979 (78). The mean hospital bill for 41 resuscitated patients with discharge diagnoses of cardiopulmonary arrest who required active interventions was $7,235; the mean stay in the ICU for these patients was 4.3 days (out of a total average stay in the hospital of 12.2 days). The hospital charges for these patients generally reflected the patient's length of stay in the ICU, the length of the patient's total stay in the hospital, and the degree of intervention needed.

Reimbursement for Resuscitation

The Federal Government bears a large share of the costs generated by resuscitation of elderly people. The reason is that virtually all individuals who are successfully resuscitated are admitted to a hospital, and hospital care for most elderly patients is reimbursed by Medicare. Under Medicare's Part A (Hospital Insurance) prospective payment system (PPS), each hospitalized patient is assigned to a diagnosis-related group (DRG) on admission to the hospital (see ch. 2). Patients admitted in cardiac arrest may be assigned to the DRG category for cardiac arrest (DRG 129); patients who suffer an arrest while in the hospital, however, have typically been assigned to a DRG other than DRG 129 at the time of hospital admission (14).

Medicare's hospital payment rates are higher for some DRGs than for others, depending on the average cost of care associated with each diagnosis. Anecdotal evidence suggests that hospitals try not to assign patients to DRG 129 because the Medicare payment rate for DRG 129 is less than for other DRGs to which these patients may reasonably be assigned (14).

The Federal Government also pays for care administered in Veterans Administration (VA) hospitals. OTA has not determined the number or proportion of elderly patients resuscitated in these hospitals or the costs of their care.

Emergency medical services that administer CPR in the community are funded from a variety of sources, including Federal, State, and local governments and private insurers. Some communities have emergency medical services that are run on a volunteer basis, without government subsidies, and these services usually do not charge patients. Medicare Part B (Supplementary Medical Insurance) covers some charges associated with CPR in the community.

OUTCOMES OF RESUSCITATION

Clinical Outcomes

Resuscitation can deliver a person from the brink of death. It can restore a patient to his or her prior lifestyle within a few weeks, with only bruises and soreness as reminders of the ordeal. Fortunate patients can resume their everyday activities, as the following case illustrates.

> **Mrs. W. had been hospitalized for intestinal problems. She was 83 years old, and the profuse diarrhea of the past week had caused tremendous weakness, made worse by the fact that she had continued to take the diuretic prescribed for her high blood pressure. Thus, she was not only dehydrated, but her blood potassium level was low, causing weakness and a predisposition to dangerous cardiac arrhythmias.**
>
> **As she was sitting in the hallway, waiting for her admission chest X-ray to be taken, she suddenly slumped in the wheelchair and slid to the floor. A nurse who was passing rushed to Mrs. W's side as she fell to the floor. The nurse felt her neck for a pulse and, feeling none, gave her a fist-thump on the chest. "Code blue" was announced on the loudspeaker and people rushed to the scene with a cart of equipment. An EKG machine attached to her arms and legs showed ventricular fibrillation. Paddles from the defibrillator were applied to the chest and current applied. Her body jerked with the shock and she began gasping for air. Regular heartbeat and blood pressure were reestablished, and she was taken to the ICU, where she was monitored for 24 hours and discharged to the ward.**
>
> **She developed pneumonia after the resuscitation, but it responded to antibiotics and her heart rhythm remained stable after the blood potassium level was restored to normal. In 10 days she was home again, living independently (14).**

For most patients, the outcome of CPR is not so positive. Some patients who are successfully resuscitated face a long, difficult recovery, and some never resume their normal daily activities. Others survive with serious physical impairment or brain damage.

If a person's blood circulation stops or is inadequate for more than a few minutes, he or she may suffer brain damage due to lack of oxygen. On average, 1 in 20 patients who survive a cardiac arrest has severe brain damage (16). In rare cases, such brain damage can lead to prolonged coma. Although elderly people may be more vulnerable than younger people to oxygen deprivation, there are no data on the incidence of new neurological deficits in elderly patients following resuscitation.

Many patients who receive CPR do not survive. The following case is one example.

> **. . . Resuscitation was in progress . . . Several people were there, watching, with no specific task. More people trickled in to watch or help as the minutes ticked by, and at one point there were 14 people in and around the room. At times a tall, somber chaplain would appear, crane his neck, speak briefly to a nurse or doctor, and then re-**

turn to a small waiting room where four family members were sitting.

After 2 hours, the doctors and nurses stopped trying. The chaplain reported that a daughter wanted to see her father.

Reluctantly, she was allowed in. As people slowly filed out and started cleaning up, the daughter desperately pleaded, "Dad! Come back! Come back, Dad! It's me, . . . come back for *me*, Dad!" After she saw no response, the chaplain took her back to her family. A nurse firmly pulled the curtain around the bed (14).

Some patients die despite repeated resuscitation over a period of hours. A "spiraling down" effect is often seen in these patients, as they arrest and are resuscitated again and again, growing continually weaker (74).

If resuscitation is unsuccessful in a hospital, death is generally accompanied by chest compression, a tube in the throat, needles stuck in the groin and elsewhere, and possibly several high-energy electrical shocks. In extreme cases, a needle is inserted directly into the heart or the chest is opened and ribs broken to directly massage the heart. It is not known how the dying person perceives this process, if at all, or whether the process increases the suffering associated with death. Most patients who die during CPR are unconscious (4). In the very few studies asking survivors about their memories, most have no memory of any part of the resuscitation process, although, as discussed below, some say they would not want it done again (6,30).

Long lingering death after CPR appears to be the publicized exception rather than the common occurrence (6). Most patients who die following resuscitation do so within the first few days.

The medical literature on outcomes of resuscitation exhibits several methodologic problems in addition to the limitations already described for utilization data. The greatest problem in comparing available studies is that different studies use different definitions of *success* (e.g., restoration of a spontaneous pulse, restoration of circulation, or remaining alive for 24 hours) and different definitions of *survival* (e.g., living until discharge from hospital, for 1 month, for 6 months, for a year, or more). The way these terms are defined determines, to a large extent, the outcomes that are reported (14).

Although widely varying success rates have been reported, on average, one-third to one-half of CPR attempts in hospitals are initially successful. For patients with cardiac arrhythmias, the initial success rate is better—about two thirds of CPR attempts with these patients initially succeed. Not all patients who are successfully resuscitated recover enough to be discharged from the hospital, however. Only about one-third to one-half of those who are successfully resuscitated (approximately 10 to 25 percent of those for whom CPR is attempted) survive long enough to be discharged from the hospital.[4]

Very little information is available about the outcomes of CPR in nursing homes. One study of 1,918 persons admitted to a New York State nursing home over an 8-year period found that only 32 persons (2 percent) received CPR in the facility. Of these, 9 persons (28 percent) survived more than 24 hours, and 5 of the 9 (16 percent of all those who received CPR) were still alive 30 days later (42).

The hospital admission rate for patients resuscitated in the community is a practical measure of the initial success rate of community CPR. Using this measure, several studies indicate an average success rate of 35 percent (range 23 to 44 percent) for community CPR (14). Among persons who are successfully resuscitated in the community and hospitalized, the percentage who recover enough to be discharged from the hospital varies greatly, depending on the cause of their cardiac arrest, whether the cardiac arrests were witnessed, how soon after cardiac arrest CPR was initiated, and whether paramedic care or only basic life support was provided (21).

Long-term survival of patients resuscitated in any setting is rare (14,69). Recurrent sudden cardiac death is the most likely eventual cause of death in those initially surviving cardiac arrest.

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[4] These overall averages are based on reviews of the literature by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (69) and by Cassel, et al. (14).

Factors That Affect the Clinical Outcome of Resuscitation

A patient's underlying diagnosis and severity of illness are major determinants of resuscitation outcome (6,15,30). One study of 294 patients resuscitated in a Boston hospital found, for example, that although 14 percent of the patients survived to leave the hospital, no patients who had metastatic cancer or pneumonia and only 2 percent of patients with renal failure survived to leave the hospital (6). Patients with multiple diseases usually fail to recover from cardiac arrest despite prolonged CPR and eventually die through failure of one organ system or another (57).

A patient's level of functioning prior to cardiac arrest is a predictor of outcome of resuscitation (6,15). One study found that only 4 percent of patients who had been homebound prior to their cardiac arrest survived cardiac arrest and CPR, compared to 27 percent of patients who had been active outside the home before their cardiac arrest (6).

The nature of a patient's cardiac arrest is another strong predictor of outcome. Patients with ventricular fibrillation are more likely to survive than patients with asystole or electromechanical dissociation (6,21). Patients with ventricular tachycardia have intermediate success rates (89).

Some CPR procedures are not effective when certain heart irregularities are present. Defibrillation, for example, is an effective means of restoring heartbeat for patients with ventricular fibrillation but not for patients with asystole (37). Likewise, pacing can be effective for asystole but is ineffective in treating ventricular fibrillation and electromechanical dissociation (72).

The time between occurrence of the cardiac arrest and initiation of resuscitative measures—"down time"—greatly influences the patient's chance of recovery. In the past decade, at least nine studies have found that survival following cardiac arrest is related to early initiation of CPR (21).

Long-term survival in patients resuscitated after a delay of more than 5 minutes has been documented, but the chance of brain damage increases (16,21). The 1974 American Heart Association standards stated:

> The technique of CPR is most effective when started immediately after cardiac arrest. If cardiac arrest has persisted for more than 10 minutes, CPR is unlikely to restore the victim to his prearrest central nervous system status (62).[5]

Duration of the resuscitative effort is also a strong predictor of outcome. As duration increases, survival rates decrease. Resuscitation efforts lasting longer than 30 minutes are usually unsuccessful (6,16,57). Some patients have recovered completely following 2 to 3 hours of resuscitative effort, but such cases are usually associated with hypothermia in drowning or with drug overdose (14).

The relationship of outcome to the number of resuscitative attempts that a patient receives during a single episode has not been determined. The poorer outcomes observed with more resuscitation attempts in some studies may be due to the longer total duration that naturally accompanies a greater number of attempts.

A patient's age is not a good predictor of the outcome of resuscitation (6,14,15,30,31,32,48,68). Some studies show no significant difference between success rates for elderly and younger patients (see, e.g., references 6 and 15). Other studies (e.g., reference 30) show that elderly patients as a group have somewhat poorer outcomes than younger patients but that the poorer outcomes in elderly patients reflect the higher prevalence of multiple diseases in these patients. Although the likelihood of multiple diseases increases with age, any particular older individual may not be affected. Thus, all these studies support the conclusion that a patient's age alone is not a good predictor of resuscitation outcome.

Within the elderly population, the initial success rate for CPR does not decrease significantly in older age groups (12,14,32). One study of 1,345 persons who received CPR in the community found no significant difference in the percentage of patients in four age groups over 65 (ages 65 to 69; 70 to 74; 75 to 79; and 80 to 99) who were resuscitated and hospitalized. The percentage of successfully resuscitated patients who recovered enough to be discharged from the hospital, however, decreased significantly with age—from 15 percent of patients aged 65 to 69 to only 8 percent of those aged 80 to 99 (79). Thus although patients in the very old age groups were successfully resuscitated as often as patients aged 65 to 69, patients in the very old age groups were less likely to survive to be discharged from the hospital.

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[5] The brain may be viable for a longer period of time in special cases of barbiturate and sedative overdose, hypothermia, and drownings.

The same study (79) found that cardiac arrest was witnessed more often for elderly patients. Yet bystanders provided CPR prior to the arrival of paramedics more often for younger patients.

Use of Other Life-Sustaining Technologies Following CPR

Following resuscitation, many patients require not only admission to an ICU or CCU and extended hospitalization but also invasive hemodynamic monitoring, prolonged mechanical ventilation, or dialysis. In one study, 78 percent of the patients admitted to hospital ICUs for a cardiac arrest required such a major intervention (18).

The life-sustaining technology most likely to be required for patients who survive resuscitation is mechanical ventilation (14). Respiratory function is often inadequate immediately after successful resuscitation, and recovery to independent breathing may take days or weeks. There is some evidence that outcome for patients receiving ventilatory assistance following CPR is not as good as that of other patients (88), probably because patients requiring such assistance tend to be more ill in general than patients who do not need such assistance.

Complications and Injuries Associated With CPR

Resuscitation can be accompanied by a wide array of complications and potential injuries that may be long-lasting and even life-threatening, particularly for individuals who are already seriously ill.

Brain damage is the result of cardiac arrest and the consequent interruption in the supply of oxygen to the patient's brain. Some people think of it as a complication of resuscitation, and, in fact, delayed initiation of CPR and inadequately performed CPR increase the risk of brain damage in persons who are successfully resuscitated.

Each of the various basic and advanced life support procedures carries its own set of risks and potential complications. The major problems that may be encountered as a result of procedures used during resuscitation are summarized in table 5-1.

The most common resuscitation-related injuries include rib fracture, collapsed lung, ruptured stomach, and broken teeth. In survivors of resuscitation, these problems can cause pain, make breathing difficult, impede weaning from a mechanical ventilator, or produce other problems that complicate postresuscitative care.

Little information is available about the incidence of resuscitation-related injuries, but one study of 63 survivors of cardiopulmonary arrest found such injuries in over 25 percent of the patients (10). Elderly patients, because they are more likely to have osteoporosis (brittle bones), are at an increased risk of fractures, but no age-specific data are available to indicate whether such injuries are more common in elderly survivors of resuscitation than younger ones (14).

Psychological Outcomes of Resuscitation

In the aftermath of a cardiac arrest, many survivors experience psychological repercussions. Several of the resuscitated patients in a study at Beth Israel Hospital in Boston reported that the hardest part of their subsequent hospitalization was adjusting to "feeling sick" and dealing with their new loss of independence (6). Depression was present in most of these patients at the time of their discharge, although it tended to resolve itself within 6 months. Every resuscitated patient in this study, regardless of age, reported some decrease in daily activities. In many cases, the fear of another arrest led patients to regulate their daily lives and limit their activities to ensure immediate access to medical care.

Surveys of patients' attitudes towards resuscitation indicate that some survivors do not wish to be resuscitated again, although they had not been opposed to their first resuscitation and they are content with their present quality of life. One study found that when 38 survivors of resuscitation were asked if they would choose to be resuscitated in the future if it were necessary, 21 (55 percent) said yes, 16 (42 percent) said no, and 1 was ambivalent. At a followup 6 months later, three patients had changed their minds: two patients no longer desired resuscitation and one said she would choose it (6).

Resistance to a second resuscitation seems to be found particularly among older survivors. A study in a hospital in Nuremberg, Germany, found that older survivors of resuscitation tended to be more negative about resuscitation than younger survivors (30). Eighteen 6-month survivors, all of whom were satisfied with their current life and state of health, were asked about their opinions toward resuscitation. All of the nine survivors under age 60 said they would agree to another resuscitation, but seven of the nine survivors over age 60 said they would not (the other two had no opinion). Similarly, six of the nine survivors under age 60 thought it reasonable to resuscitate aged persons under all circumstances, and three thought it reasonable only with certain indications. In contrast, seven of the nine survivors over age 60 thought it reasonable to resuscitate aged persons only on certain indications, and two had no opinion.

Table 5-1.—Potential Complications Associated With Specific Resuscitation Procedures

Basic life support procedures:
- regurgitation
- aspiration
- gastric distension (with mouth-to-mouth)
- rib fracture
- collapsed lung
- ruptured stomach
- spinal cord compression

Tracheal intubation:
- insertion of the tube into the esophagus
- trauma to the trachea or esophagus
- damage to the vocal cords
- narrowing of the trachea following tube removal

Defibrillation:
- myocardial necrosis (damage to heart muscle)

Precordial thump:
- a more dangerous heart rhythm

Drugs:
- *Sodium bicarbonate (in excess)*
  —alkalosis
  —sodium and water overload
  —paradoxical cerebral spinal fluid acidosis
- *Atropine*
  —ventricular fibrillation
  —tachycardia
  —increased oxygen demand by the heart with increased heart rate
- *Calcium chloride*
  —intracellular damage

Temporary cardiac pacemakers:
- *External pacers*
  —severe muscle contractions
  —local tissue burns
- *Transvenous pacers*
  —local trauma
  —infection
  —laceration of the heart muscle
  —blood clots
  —ventricular arrhythmias
- *Transthoracic pacers*
  —collapsed lung
  —heart injury, including laceration
  —laceration of blood vessels

SOURCES: C.K. Cassel, M.D. Silverstein, J. LaPuma, et al., "Cardiopulmonary Resuscitation in the Elderly," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, November 1985; R.H. Falk, L. Jacobs, A. Sinclair, et al., "External Noninvasive Cardiac Pacing in Out-of-Hospital Cardiac Arrest," *Critical Care Medicine* 11(10): 779-782, 1983; and J.R. Roberts and M.I. Greenberg, "Emergency Transthoracic Pacemaker," *Annals of Emergency Medicine* 10(11): 600-612, 1981.

MAKING DECISIONS ABOUT RESUSCITATION

In the first 15 years following the development of CPR, physicians tended to implement both basic and advanced life support measures without hesitation whenever the need arose. Over time, however, there has been a growing recognition among physicians and others of problems associated with resuscitation, particularly the low chance of success and the risk of debilitating or life-threatening complications.

In 1976, the *New England Journal of Medicine* published two articles on withholding life support, particularly resuscitation, from terminally ill patients (20,70). An accompanying editorial entitled "Terminating Life Support: Out of the Closet" (29) praised the two articles for making public the "open secret" that resuscitation (and other life-sustaining treatments to a lesser degree) were being withheld or withdrawn from some terminally ill patients.

Since then, criteria and procedures for deciding to withhold CPR have been widely analyzed and debated. Although debate about these criteria and procedures continues, it is now generally accepted that CPR is not an appropriate treatment for *every* patient in cardiac arrest. A strong presumption in favor of resuscitation remains, nevertheless. As one observer has noted:

> [CPR] is the only medical intervention that can be performed by nonphysicians without a physician's order; a physician's order is required only *if CPR is to be withheld*, even in the patient's home (90).

In the case of persons who experience unexpected cardiac arrest in the community and in the case of most patients in hospitals and other health care facilities, it is assumed that CPR should be attempted, because the alternative for the individual is certain death. For some patients, however, CPR is withheld. Withholding of CPR may occur as the result of a unilateral decision made by a physician at the time of the person's cardiac arrest. Alternatively, CPR may be withheld on the basis of a prior decision by the physician sometimes in consultation with other health care providers, the patient, and/or the patient's family. In such cases, a DNR order—a directive to withhold CPR—may be written in the patient's medical chart.

This section discusses the factors that affect physicians' decisions to withhold CPR, the usual role of physicians, nurses, and patients and their families in the decisionmaking process, what is known about the current use of DNR orders, and problems associated with their use. The same factors are associated with physicians' decisions to withhold CPR as reflected in research on: 1) their stated attitudes about which types of patients should not receive CPR; 2) their actual decisions to withhold CPR, especially in hospitals; and 3) their decisions about which patients should have a DNR order. Data from all three sources are summarized below.

Factors That Affect Physicians' Decisions About Resuscitation

Many factors enter into physicians' decisions about whether resuscitation is appropriate for a given patient. First and foremost are indicators of the potential for successful outcome. Physicians are not obliged to provide futile or useless treatment, and a decision not to resuscitate is generally considered appropriate when CPR would be futile (51). Thus, a patient's underlying diagnosis and other determinants of resuscitation efficacy (see "Outcomes of Resuscitation") are important considerations in physicians' decisions to withhold CPR.

The presence of a terminal illness in a patient is frequently mentioned by physicians as a reason for withholding CPR. In the Portland, Oregon area, 87 percent of 78 emergency medicine physicians surveyed said they would stop CPR on a patient in the end stage of a terminal disease (16). Similarly, cancer was the most common diagnosis of patients in one Boston hospital who died without receiving resuscitative measures (6), and several studies have shown that patients with cancer are more likely than other patients to have a DNR order (25,73).

Severity of illness is another frequently mentioned factor in physicians' decisions about resuscitation. Many physicians believe that resuscitation should be withheld from patients with multiple or severe diseases that are chronic, progressive, or irreversible (15,40). Some physicians argue that although CPR is technically possible in such patients, it is right to exclude patients with chronic, progressive, disabling diseases who are highly dependent on others (32).

Some physicians believe that it is appropriate to withhold CPR from some patients who have severe illnesses but who are not terminally ill. One study of DNR orders in a medical ICU found that a patient's severity of illness was the most important predictor of his or her DNR status, but over 60 percent of patients with DNR orders did not have a diagnosis of terminal illness (91). Likewise, in a community hospital, 40 percent of those with DNR orders did not have a terminal illness documented in their medical record (49).

Another factor that is considered in resuscitation decisions is "down time." The Portland study of emergency medicine physicians found that 44 percent said they would cease CPR if it had been initiated in the community more than 10 minutes after the patient went into cardiac arrest (16). Down time is associated with brain damage, as discussed earlier, and one expert in resuscitation has cautioned that "litigation is more likely to follow when the patient survives (a cardiac arrest) with permanent brain damage than when the patient dies" (56).

In addition to factors that have been shown to affect the medical outcome of resuscitation, such as severity of illness and "down time," several other factors that do not affect the medical outcome of resuscitation often play an important role in physicians' attitudes and decisions about its use. One such factor is the patient's mental status. When presented with case descriptions of one demented and one mentally retarded patient in cardiac arrest and two cognitively normal patients also in cardiac arrest, 63 physicians in a Philadelphia internal medicine residency program said that they would be less likely to initiate CPR on the demented and mentally retarded patients than the cognitively normal patients (27). Likewise, the Portland study found that 54 percent of the 78 physicians stated that they would cease CPR if they learned that a patient had a known severe mental impairment, such as dementia or mental retardation (16).

A patient's mental status may also influence physicians' decisions about whether a patient should have a DNR order. In one Boston hospital, 49 percent of patients who were given a DNR order had abnormal mental status (i.e., they were comatose or disoriented), compared to only 15 percent of a control group of patients who did not have abnormal mental status (73). In another hospital, terminally ill patients who were mentally alert were generally not given a DNR order (36).

Another factor that influences resuscitation decisions is a patient's residence in a nursing home. One study found that the knowledge that a patient in cardiac arrest had been admitted to the hospital from a nursing home was enough to discourage some physicians from continuing CPR; 18 percent of 78 emergency room physicians surveyed in Oregon said they would cease CPR if the patient had been transferred from a nursing home (16). Another study found that patients who were admitted from a nursing home were three times more likely to be given a DNR order than a matched control group of patients who were not admitted from a nursing home (73).

Finally, although research shows that patient age alone does not alter the outcome of resuscitation and many authors recommend against the use of age as a factor in decisions about CPR (40,55,59), in practice, age plays a significant role in these decisions (15,19). Gordon and Hurowitz described a bias against elderly patients in physicians' decisions about whether to administer CPR:

> For younger patients, a physician's decision not to resuscitate is usually made after conscious deliberation. This is not always so for the elderly, and yet, most physicians do not resuscitate many of their elderly patients. It is not clear at precisely what level the decision to resuscitate is made, but

> in the majority of elderly deaths, CPR attempts have not been carried out (31).

A survey of physicians in a Philadelphia internal medicine residency program found that a patient's age influenced their attitudes about whether to administer CPR. When presented with two hypothetical cases, one of a 32-year-old patient with a pulmonary embolism and the other of a 98-year-old patient with the same condition, all of the 63 physicians responding to the survey stated that they would be much more likely to resuscitate the younger patient than the older one. The physicians' disinclination to resuscitate older patients was also evident, although less strongly, when the age of the older patient was changed to 64 (27).

There is some evidence that the patient's age is a predictor of DNR designation. A study of ICU patients in a Cleveland hospital found the average age of the 71 patients with such orders was 66 years, while the average age of the 435 patients without DNR orders was less than 58 years (91). This difference could not be solely attributed to the facts that DNR patients are usually seriously ill and that the incidence of serious illness increases with age, because 166 seriously ill patients without DNR orders had an average age of less than 61 years.

The rationale for the use of a patient's age as a factor in decisions about administering CPR is not clear. Some physicians may not resuscitate elderly patients particularly in instances of unobserved cardiac arrest or when the effort is not promptly successful because of their perceptions that CPR may simply prolong the process of dying and that many elderly patients fear death less than prolonged dying or dependence on others. According to one physician:

> The vast majority of my patients over 65 tell me that 1) they do not dread death, and hope that theirs will be sudden; and 2) they do fear incarceration in a nursing home or total dependence on others (3).

Another physician, who asked 153 decisionally capable elderly (aged 66 to 98 years) nursing home residents whether they wanted to receive CPR in the event of a cardiac arrest found that 77 residents (50 percent) did not want CPR; 11 residents (7 percent) did want it; 64 residents (42 percent) wanted their physician to choose at the time; and 1 did not respond. Considering the large number of residents who did not want CPR, that physician concluded:

> Although age alone does not preclude candidacy for CPR, the changed attitudes and values of old people are at least as germane to case selection as are any other consideration. As a group, the elderly tend to be realistic and to often recognize . . . that sometimes "death is the best life has to offer" (86).

The Decisionmaking Process

A patient's physician has the authority to make a decision about initiating or withholding CPR, but he or she may not be available at the time the decision must be made. Many other individuals may also be involved in the decisionmaking process. The urgency of the event and the involvement of many people with different points of view and different information about the patient can create a complex and sometimes chaotic situation, as illustrated in the following case:

Mr. R, 65 years old, is brought into the emergency room by ambulance. The emergency room staff determines that he suffered a heart attack and was not breathing for an unknown period of time before he was resuscitated by paramedics.

After initial evaluation, Dr. A, the family physician, tells Mrs. R that her husband's condition is serious and that he may have suffered irreversible brain damage. Before he leaves for his office, Dr. A also says that he is ordering a neurological consultation and that he wants to monitor the situation for the next 72 hours.

In the waiting room, Mrs. R encounters Ms. C, the chaplain's intern assigned to the emergency room. Over coffee, Mrs. R confides to Ms. C that she and her husband had talked about the possibility of such an event and that both wished that "nothing extraordinary should be done to keep them alive." Ms. C also learns that Mrs. R had not given this information to Dr. A; she makes a mental note to do so. Meanwhile, other families occupy her attention.

Approximately 1 hour later a "Code blue" is called. Mr. R has suffered a cardiac arrest. By the time Ms. C responds to the code, the code team

has begun work. Ms. C relates the substance of her conversation with Mrs. R to the nursing supervisor who passes it on to the resident in charge of the code team. The resident is furious with the nurse for interrupting his efforts by reporting "gossip."

The supervisor pages Dr. A., who responds immediately from his office. She communicates the substance of the conversation between Ms. C and Mrs. R, the fact that Mr. R has coded, and that the code team is now working on him. The chaplain's report rings true to Dr. A. He has had a longstanding relationship with the family and feels that he knows what they would want, even without a direct conversation.

By now the resident has come to the phone. He is angry that Dr. A is even considering the secondhand report. He tells Dr. A that Mr. R can be resuscitated, although his prognosis would still be uncertain.

Dr. A orders the resident to stop the code, and tells him that he will call Mrs. R and inform her that her husband has died. The resident hangs up the phone and heads toward Mr. R's room. Just then a nurse comes into the hallway, shouting, "He's starting to come back!" The resident turns toward Ms. C and asks angrily, "What am I supposed to do now?" (34).

Potential Participants in Decisions About Resuscitation

In general, only a physician may decide to withhold CPR. Emergency rescue teams have standing orders to initiate CPR as quickly as possible. In hospitals, staff members are generally required to initiate CPR unless there is a physician's order not to resuscitate a particular patient.

In hospitals that have staff physicians, residents, and interns, these individuals frequently make decisions about resuscitation. A study in one hospital found, for example, that the patient's physician was involved in decisions to withhold CPR in only 39 percent of cases, and residents and interns made the decision in the other cases (80).

Nurses cannot legally make decisions about resuscitation, yet research indicates that they often have strong feelings about whether their patients should be resuscitated. It is not known how often nurses are involved in such decisions. One study found that nursing involvement in decisions about DNR orders had been documented in only 10 percent of cases; however, nurses had played an active role in assessing the patient's and family's attitudes about the patient's condition and treatment and encouraging open discussion between the patient and the physician about the patient's resuscitation status (7).

In the event of a sudden and unexpected cardiac arrest, a patient cannot participate in the decision about whether to resuscitate, and the involvement of the patient's family is severely limited by time constraints. In the great majority of cases, however, advance deliberation is possible, and patients and families can be involved in decisionmaking.

Patient and Family Involvement in Decisions About Resuscitation

Physicians once made decisions about whether to resuscitate patients behind closed doors, paternalistically protecting their patients from what the physician believed would be upsetting for the patient. Recent legal developments and changing attitudes of the public as well as many physicians support the rights of decisionally capable adults to be informed about their medical condition and to participate in decisions about their medical care, including resuscitation (1,64).

Yet patients are not always consulted about their desire for CPR. The findings of one study suggest that although many physicians believe that patient participation in resuscitation decisions is important, they often do not act accordingly (5). The researchers interviewed 157 physicians involved in the care of 154 patients who had been resuscitated (24 of the patients survived). Almost all the physicians said they believed that patients should participate in decisions about resuscitation, but only 10 percent of the physicians had actually discussed resuscitation with their patients prior to the patient's cardiac arrest (5).

Almost all the physicians interviewed thought they knew what their patients would want, but their opinions correlated only weakly with the preferences expressed by the 24 surviving patients, particularly the patients who did not want to be resuscitated. For example, although 8 of the 24 patients stated that they had not wanted CPR, only 1 of the 16 physicians caring for these 8 patients was aware of this preference; 10 of the physicians thought their patients wanted CPR; 3 thought their patients were ambivalent, and 2 had no opinion (5).

Other studies indicate that patients are usually not involved in decisions about DNR orders. A study of 95 patients with DNR orders in a Boston hospital found that consent for the DNR order had been given by the patient in only 18 percent of the cases. The family had given consent in 66 percent of the cases (73). A study of DNR orders in one ICU found that patients' wishes were listed as a reason for the decision in only 15 percent of the cases. There were no written justifications for the DNR orders in 42 percent of the cases, but in cases where there was documentation, it more commonly included poor prognosis (59 percent) or the perception of poor quality of life (24 percent) than patient preferences (91).

At the time decisions about DNR orders are made for them, many patients of all ages are not decisionally capable. In one ICU, 55 percent of patients with DNR orders were unable to participate in decisionmaking because of coma or reduced consciousness (92). In another hospital, 76 percent of patients for whom a DNR order was written were unable to participate in the decision as a result of preexisting dementia, newly acquired coma, or other conditions that caused reduced consciousness or cognitive impairment. Only 11 percent of the patients, however, had been too cognitively impaired to participate in decisionmaking at the time of their admission to the hospital (7).

Even for patients who are decisionally capable, physicians may consult the family rather than the patient. A study of DNR orders in three Texas teaching hospitals found that the patient and/or family was involved in 83 percent of decisions not to resuscitate; in at least 20 percent of these cases, the decision was discussed with the family, not the patient, even though the patient was considered decisionally capable (25). As one ethicist has noted, failure to involve decisionally capable patients in a decision to withhold CPR in the event of a cardiac arrest is a serious ethical problem (85).

Decisions to resuscitate may be discussed with patients and families even less often than decisions not to resuscitate (90). In the three Texas teaching hospitals mentioned above, researchers found that physicians' decisions that patients should be resuscitated in the event of cardiac arrest had been discussed with only 22 percent of the affected patients or their families (25).

Some physicians refrain from discussing resuscitation with their patients in order to protect them or because they feel it is unnecessary to bring up the issue (5). Some physicians also believe that patients will initiate a discussion about resuscitation if they wish. Many patients, however, believe that physicians would rather not discuss treatment options, particularly if the discussion might lead to an emotional scene, might take a lot of time, or could be interpreted as implying lack of trust (1). In addition, many physicians have difficulty discussing issues related to death or dying (see ch. 10). As one physician has noted, finding the "right time" for such discussions is also difficult:

> Despite all arguments favoring open discussion, it is difficult to broach the issues of death and treatment limitation with a patient or family. No time seems like the right time. When patients are relatively healthy, we do not want to upset them needlessly; when they are terribly sick, we do not want to upset them further. If we wait too long, they may become incompetent. There is no simple answer to this question of timing. In general, it is easier if discussions about these issues have been part of the ongoing physician/patient relationship, instead of being precipitated for the first time by a crisis (90).

Some physicians and other health care providers are more reluctant to discuss treatment options with older patients than younger ones. This may be because they assume that older patients prefer to have treatment decisions made for them; because they assume that older patients will not understand the discussion; or because older patients are more likely than younger ones to have hearing or speech impairments that may interfere with communication. Thus, elderly people may be less likely than younger people to be involved in decisions about their treatment.

Disagreement Among Participants in Decisions About Resuscitation

Even when patients and their families are consulted, decisions about resuscitation are not easily made. A consensual decisionmaking process that involves many people may remove the full burden of the decision from the shoulders of the physician, but can also make the process even more difficult.

Family members may disagree about the appropriate treatment, as the following case illustrates:

> **A man was hospitalized with end-stage cardiac and respiratory disease. He was virtually comatose. His wife and two children had decided, after much agonizing, to request a DNR order. The doctor wrote the order on the chart. That evening, when the family was at dinner, the third child arrived from out of town. He was in his father's room when his father suffered a cardiac arrest. The son rang the bell and screamed at the nurse, "Do something, do something!" (17).**

A patient's physician and staff physicians, residents, and interns may also disagree about whether the patient should be resuscitated. OTA is not aware of any research on the frequency of such disagreements when a decision about resuscitation is made without advance deliberation at the time of a patient's cardiac arrest. One study of DNR orders at three Texas hospitals, however, found that staff physicians disagreed with the decisions about DNR made by patients' physicians for 43 (6 percent) of the 758 patients: only 1 of the 43 disagreements involved a patient who had a DNR order; the remainder involved patients whom staff physicians thought should have a DNR order but did not (25).

Sometimes nurses disagree with patients' physicians and with staff physicians, residents, and interns about the appropriate treatment decision for a particular patient. Although the patient's physician is ultimately responsible for the decision, several observers argue that physicians should carefully consider decisions about a patient's DNR status that meet with persistent, thoughtful disagreement from staff nurses. They point out that nurses sometimes have a greater awareness of patient and family emotional responses and treatment preferences than the physician (50,90).

In some instances, a physician may disagree with the patient or family about whether resuscitation should be provided. Some physicians who disagree with a patient's or family's directive not to resuscitate override that directive. A physician may do this when a patient is not terminally ill or has few serious conditions. In such cases, the physician acts in what he or she considers the patient's "best interest," reasoning, for example, that "resuscitation is not what the patient meant when she said that she wanted no extraordinary measures taken," or that "the patient was just depressed when he signed the DNR order and will be thankful later" (4,11).

Conversely, some physicians override a patient's or family's wishes for treatment when they believe that their demands for resuscitation are unreasonable or that treatment will not benefit the patient (51). Unilateral decisions by physicians not to provide CPR when the patient or family has requested it are controversial, however, and increase risk of litigation. To avoid these problems, some physicians may give a verbal order not to resuscitate the patient but fail to document the order in the patient's medical record (52).

Obtaining Informed Consent for Resuscitation

Informed consent for resuscitation is usually not obtained in any treatment setting, partly because of the strong general presumption that all patients who experience cardiac arrest should be resuscitated unless there is a physician's order to withhold CPR. Some observers have noted that the lack of a requirement for informed consent for resuscitation supports a lack of communication between physicians and patients (75). At least minimal discussion about many other invasive medical procedures is ensured because informed consent is required. Resuscitation differs from these procedures in that its need is sudden and often unanticipated. Yet advance deliberation is theoretically possible in virtually all cases.

There is currently much debate about the desirability of requiring informed consent for resuscitation at some point during a patient's hospitalization. Some observers favor such a requirement as a means of ensuring prior discussion of the resuscitation decision. According to one physician:

> It would seem that the time has arrived when all patients should have an opportunity to express their desire for or against resuscitation on routine admission to the hospital. The use of a standard written form for patients to consider on admission might force a more thorough discussion of the issue between patient and physician (75).

In a meeting of the advisory panel for this OTA assessment, the majority of panelists favored requiring informed consent for resuscitation after the first 24 hours of hospitalization for patients for whom the issue is appropriate (see box 5-A).

Other observers believe that requiring informed consent for resuscitation is unrealistic and inadvisable. They argue that requiring physicians to discuss resuscitation with all hospitalized patients who may die "would provoke unnecessary anxiety" (15).

Trying to ascertain a patient's preference about resuscitation at the time of hospital admission may be inappropriate for several reasons. At the time they enter the hospital, patients are often under emotional stress and may not be able to fully and properly consider a resuscitation decision. They may fail to fully understand the consequences of their decision or to anticipate all circumstances in which cardiac arrest might occur. Temporary depression at the time of admission to a hospital might color some patients' decisions. Finally, the vitally important decision about whether or not to resuscitate might get buried amidst the numerous questions patients must answer and forms they must sign on hospital admission.

Some nursing homes solicit residents' preferences about resuscitation at the time of admission or during their stay in the facility. The written information about CPR provided to residents by one such facility and the form used to obtain residents' responses are illustrated in figures 5-3 and 5-4. The blank spaces at the bottom of the form used to obtain residents' responses are for changes in residents' previously expressed wishes. When a resident of the nursing home is hospitalized, a photocopy of the form expressing his or her preference about resuscitation is sent to the hospital with other medical information (86).

Box 5-A.—Majority Opinion of OTA Advisory Panel Members Regarding Informed Consent for Resuscitation

- **A presumption in favor of attempting resuscitation (in the absence of a DNR order) should operate in the first 24 hours of hospitalization. There may, however, be some patients for whom a DNR order is clinically indicated during this time.**
- **During the course of hospitalization, the issue of whether to resuscitate should be discussed with patients for whom the issue is appropriate.**
- **The decisionally capable patient or family/guardian of the decisionally incapable patient should be involved in the discussion with medical staff.**
- **For the decisionally incapable patient, in the absence of a surrogate decisionmaker, the medical team should be involved in the decision.**

SOURCE: OTA Advisory Panel for Life-Sustaining Technologies and the Elderly, 1986.

Physicians' Directives About Resuscitation

The Use of DNR Orders

The use of DNR orders has at least two widely understood goals: 1) to ensure that physicians who are most familiar with a particular patient decide on the appropriateness of resuscitation attempts before such attempts are needed and without the stress induced by a sudden arrest; and 2) to encourage physicians to consult with patients, or with the families of decisionally incapable patients, to determine their wishes concerning further treatment (25).

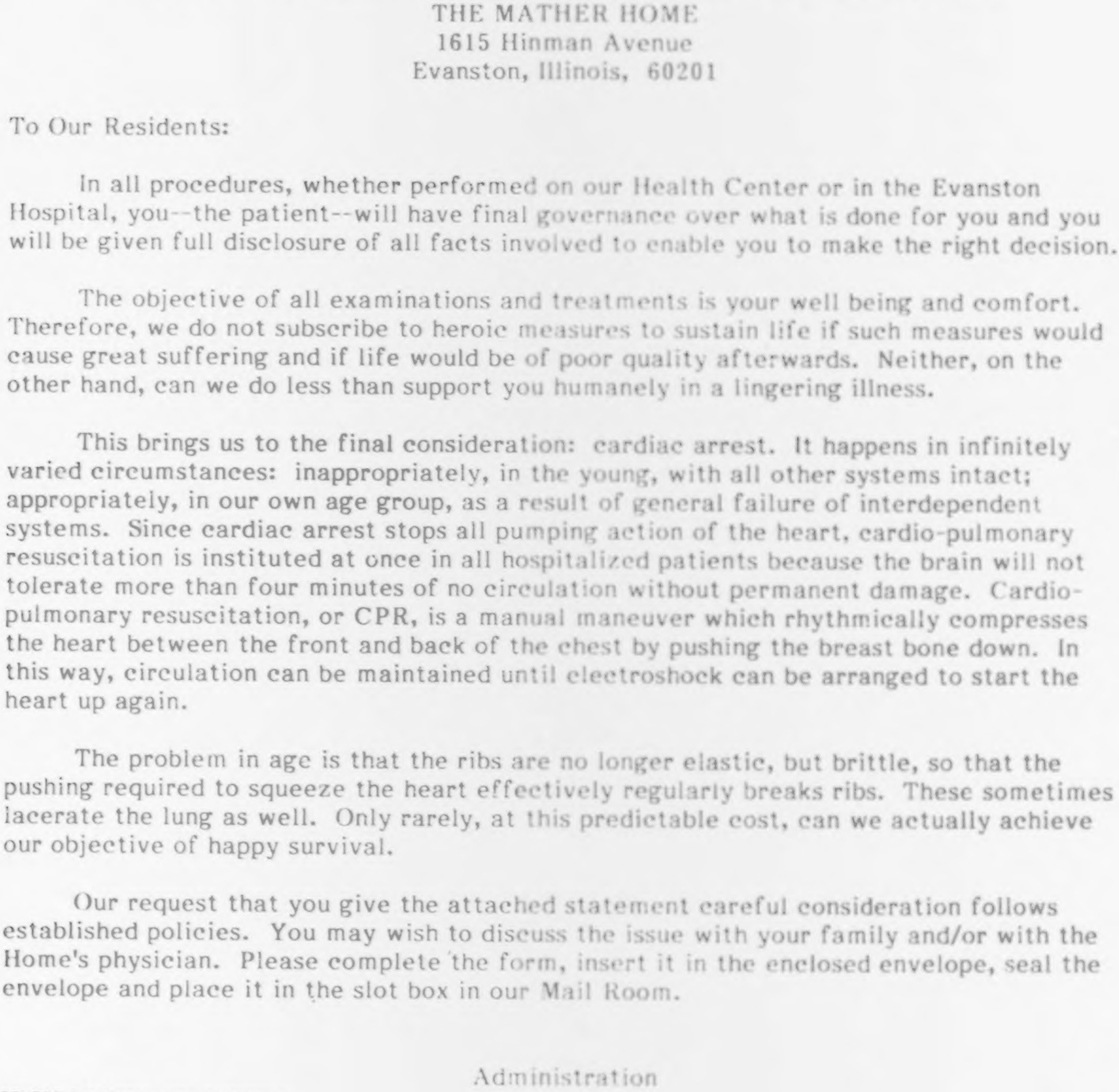
Some observers suggest that the following procedures should be followed by physicians issuing DNR orders (59):

- The physician fully evaluates the patient's medical condition.
- The physician, with the rest of the health care team, determines the appropriateness of a DNR order for the patient.
- When the patient is decisionally capable, the DNR decision is reached between the patient and physician.

- When the patient is decisionally incapable, the physician consults family members or other surrogate decisionmakers.
- If the patient or family members disagree with the DNR order, it is not implemented.
- Once the DNR decision is made, the physician discusses its meaning with the other health care personnel involved in the patient's care (59).

There are no national data on the percentage of patients with DNR orders. Data from individual hospitals indicate the percentage varies among different hospitals. Recent studies in hospitals in San Francisco and Boston have found that 3 to 4 percent of all patients have DNR orders (7,49, 52,73), whereas 9 percent of patients in three Texas hospitals had DNR orders (25).

Figure 5-3.—Information About CPR Provided to Residents of One Nursing Home



THE MATHER HOME
1615 Hinman Avenue
Evanston, Illinois, 60201

To Our Residents:

In all procedures, whether performed on our Health Center or in the Evanston Hospital, you--the patient--will have final governance over what is done for you and you will be given full disclosure of all facts involved to enable you to make the right decision.

The objective of all examinations and treatments is your well being and comfort. Therefore, we do not subscribe to heroic measures to sustain life if such measures would cause great suffering and if life would be of poor quality afterwards. Neither, on the other hand, can we do less than support you humanely in a lingering illness.

This brings us to the final consideration: cardiac arrest. It happens in infinitely varied circumstances: inappropriately, in the young, with all other systems intact; appropriately, in our own age group, as a result of general failure of interdependent systems. Since cardiac arrest stops all pumping action of the heart, cardio-pulmonary resuscitation is instituted at once in all hospitalized patients because the brain will not tolerate more than four minutes of no circulation without permanent damage. Cardio-pulmonary resuscitation, or CPR, is a manual maneuver which rhythmically compresses the heart between the front and back of the chest by pushing the breast bone down. In this way, circulation can be maintained until electroshock can be arranged to start the heart up again.

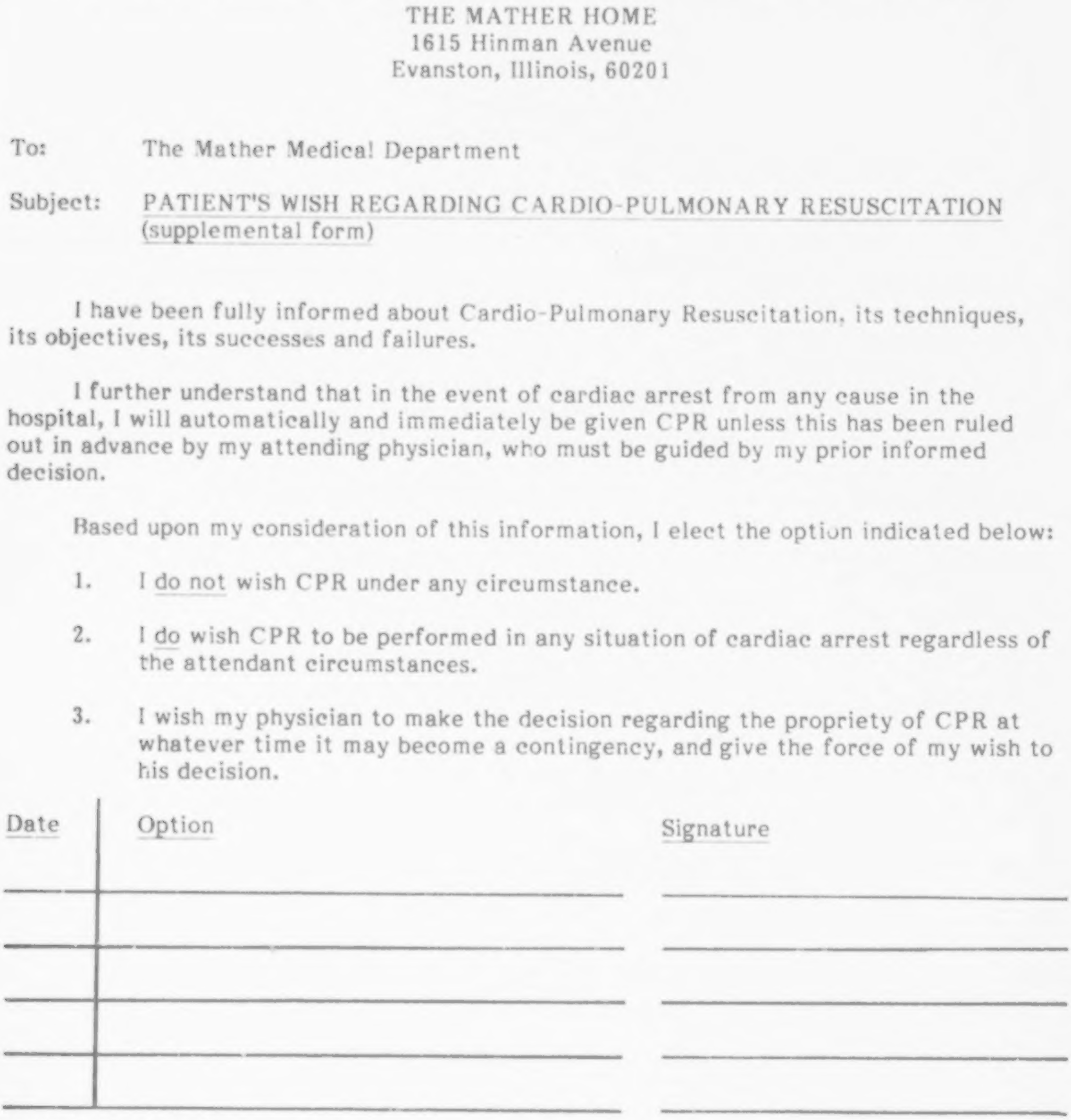
The problem in age is that the ribs are no longer elastic, but brittle, so that the pushing required to squeeze the heart effectively regularly breaks ribs. These sometimes lacerate the lung as well. Only rarely, at this predictable cost, can we actually achieve our objective of happy survival.

Our request that you give the attached statement careful consideration follows established policies. You may wish to discuss the issue with your family and/or with the Home's physician. Please complete the form, insert it in the enclosed envelope, seal the envelope and place it in the slot box in our Mail Room.

Administration

SOURCE: The Mather Home, Evanston, IL.

Figure 5-4.—Form Used by One Nursing Home To Obtain Resident Preferences About CPR



THE MATHER HOME
1615 Hinman Avenue
Evanston, Illinois, 60201

To: The Mather Medical Department

Subject: PATIENT'S WISH REGARDING CARDIO-PULMONARY RESUSCITATION (supplemental form)

I have been fully informed about Cardio-Pulmonary Resuscitation, its techniques, its objectives, its successes and failures.

I further understand that in the event of cardiac arrest from any cause in the hospital, I will automatically and immediately be given CPR unless this has been ruled out in advance by my attending physician, who must be guided by my prior informed decision.

Based upon my consideration of this information, I elect the option indicated below:

1. I do not wish CPR under any circumstance.
2. I do wish CPR to be performed in any situation of cardiac arrest regardless of the attendant circumstances.
3. I wish my physician to make the decision regarding the propriety of CPR at whatever time it may become a contingency, and give the force of my wish to his decision.

Date	Option	Signature

SOURCE: The Mather Home, Evanston, IL.

Studies in 14 ICU's across the country found that the frequency of DNR orders varied from less than 1 percent to 14 percent of all patients (91,92). These variations were not explained by differences in patient characteristics in the different ICU's and may instead reflect differences in physician attitudes toward aggressive treatment (92).

The use of DNR orders is beginning in a few nursing homes (see "Resuscitation Policies in Hospitals and Other Institutions") but is not as common in nursing homes as in hospitals. For many nursing home residents, the critical decision with regard to resuscitation is often a decision not to hospitalize the resident, thus limiting treatment to that available in the nursing home (8).

Agreement between physicians and family members about a patient's DNR status may be difficult to reach because many family members fear that a patient with DNR orders will be neglected by the medical staff. DNR policies commonly state that the administration of other forms of care should be independent of the decision to withhold resuscitation. The withdrawal of caregivers from patients with DNR orders has been clinically observed, however, and may be a particular problem for elderly patients (46).

Disaggregating Decisions About Treatment: DNI and DNT Orders

Patients and their families often come into contact with the health care system during periods of personal crisis. At such times, they may request that "no heroics" be provided or, conversely, that "everything possible" be done. These broad directives are open to a variety of interpretations by health care providers, and patients and families sometimes fail to consider or to understand the implications of their requests.

Resuscitation can be the starting point for prolonged dependence on other technologies such as mechanical ventilation. The patient and/or family members who request "no heroics" may feel quite differently about a fairly simple procedure like external cardiac massage than they feel about more invasive techniques like open-chest massage, defibrillation, and pacing. Yet there is no way to distinguish among life-sustaining technologies when wishes are expressed in global terms such as those just noted. This ambiguity demonstrates the need for clear definition of terms.

A DNR directive can itself be made clearer by the disaggregation into a variety of more specific directives. With partial codes, CPR is initiated, but drugs are not administered, intubation is not performed, or resuscitation is stopped after a predetermined period of time (51). Do-Not-Treat (DNT) orders prohibit all active treatment, while Do-Not-Intubate (DNI) orders state that the range of resuscitative efforts short of intubation may be performed. The decision of whether or not to intubate may in the mind of the patient or family be separate from the decision to administer external chest compressions (25), and some patients may desire a partial code.

"Show Codes" and "Slow Codes"

Sometimes, rather than issue a written DNR order, a physician may verbally direct staff to perform a few resuscitative procedures to reassure the patient's family that "everything was done" (51), but with the intention of letting the patient die. This has been called a "show code." A similar method that is used to reassure the family is a "slow code"—the physician may direct health care personnel on call to "Walk, not run, if the patient arrests." Or the physician may ask the nurses to page him or her personally rather than alert the CPR team over the loudspeaker. A slow code increases the chances of permanent brain damage, because in order to be effective, CPR must be instituted with all possible speed (14).

Slow and show codes are considered by many to be dishonest and entirely inconsistent with established ethical principles. Moreover, they can place caregivers in legal jeopardy (43). Yet they are frequently applied when an explicit DNR order cannot be written, either because it has not yet been discussed with the family or because there is disagreement among the family, the patient, and the physician. For patients who are not terminally ill, for example, a DNR decision is often difficult to make. The phenomena of slow and show codes has prompted some observers to call for continuing education of caregivers and other strategies to discourage these practices (65,71,90).

Legal Concerns About Physicians' Directives To Withhold Resuscitation

No caregiver has ever been found liable for a properly derived and documented DNR order, and caregivers can be held liable for battery if they resuscitate a patient against the patient's wishes. Yet there remains a wide range of beliefs regarding what the law requires (43).

Some health care professionals are reluctant to withhold resuscitation even with a DNR order because of fear of legal liability—especially if there is not unanimous agreement with the DNR order among all the concerned parties. This fear exists despite one court's ruling that the appropriateness of a DNR order is a question "to be answered in accordance with sound medical practice in consideration of the individual patient's conditions and prognosis" (38).

Caregivers are also uncertain about withholding CPR from decisionally incapable patients with no available guardian to authorize a DNR order. In rare cases, they seek recourse in the courts, but they more commonly resuscitate or perform a "slow code."

In some cases, physicians who have issued DNR orders without the knowledge of patients or their families have tried to protect themselves from liability by leaving no record of the DNR order. In 1984, a special grand jury investigating a death in a Queens, New York hospital found that the hospital had been using an informal "purple dot" system to denote which of the patients were not to be resuscitated in the event of a cardiac arrest. Nurses recorded DNR orders for hospital staff by affixing purple decals, available in the hospital gift shop, to their index cards. The nursing cards including the purple decals were destroyed after the patients died. The system insured both secrecy, since neither the patients nor their families were aware of the DNR decision, and lack of accountability for the decision (76).

In recent years, nurses have become increasingly concerned about their own legal responsibility and liability, and nurses may be particularly afraid of legal repercussions in decisions about resuscitation when all parties to the decision do not agree. Nurses are often first to respond to a cardiac arrest. If a DNR order has been written without the knowledge of or against the wishes of the patient or family, the nurse may bear responsibility for withholding CPR. Conversely, if a nurse knows the patient does not want resuscitation but the physician has not written a DNR order, the nurse could still be in legal jeopardy for initiating resuscitation. An even more difficult situation occurs when the physician gives an oral order not to resuscitate the patient, but does not write a formal order in the chart. Nurses who follow such oral orders have no documentation that the physician told them not to resuscitate and hence they risk legal liability. For these reasons, many nurses favor the establishment of explicit institutional policies for decisions about resuscitation (43,44).

Resuscitation of Patients With DNR Orders by Emergency Medical Services

The use of CPR by ambulance and other emergency medical personnel for nursing home and hospice patients who have DNR orders is an issue of growing concern. Emergency medical personnel are usually unfamiliar with a particular patient's medical background and treatment plan and usually have standing orders to resuscitate all patients in cardiac arrest (58).

In order to avoid resuscitation of patients with DNR orders, many hospices now instruct their clients not to activate the emergency medical services system (i.e., call an ambulance) for an apparently terminal event. This approach denies patients relief from severe, potentially reversible symptoms, however, and denies families assistance with difficult events (35).

One county in Minnesota has developed a policy allowing paramedics and emergency physicians to honor orders in nursing home records not to resuscitate or intubate residents (58). The patient's physician is required to document the directive in the medical record and to update it periodically. The patient with a DNR or DNI order remains eligible for hospitalization and other emergency care.

DNR Orders and Other Life-Sustaining Treatments

Many experts agree that a DNR order should not imply that other treatments will be withheld or withdrawn, and they point out that patients with DNR orders may still be appropriate candidates for mechanical ventilation, dialysis, and even surgery and chemotherapy (24,40,59,64,69,91). Research and anecdotal evidence suggest, however, that such treatments are frequently withheld or withdrawn from patients with DNR orders.

The type of care provided to patients with DNR orders varies in different hospitals. A study in one ICU found that treatments such as blood transfusions, dialysis, and mechanical ventilation were withheld from 68 percent of patients with DNR orders and withdrawn from 40 percent of patients with DNR orders (92). A study in another ICU found, however, that life-sustaining treatments were not routinely withheld or withdrawn after a DNR order was written. Ninety-eight percent of patients receiving mechanical ventilation prior to the DNR order continued to receive it afterwards. Likewise, vasoactive drugs and intravenous antibiotics were withheld from less than 25 percent of patients after a DNR order was written (91).

Another study that was not restricted to ICU patients found that life-sustaining treatments were withheld or withdrawn from 28 percent of patients after DNR orders were written. Within this group, mechanical ventilation was withdrawn from all the patients who had been receiving it before the DNR order was written; dialysis was withdrawn from 40 percent of patients who had been receiving it and withheld from 60 percent of patients for whom it would otherwise have been provided; and intravenous fluids and antibiotics were withheld or withdrawn from about half of the patients. These changes in level of care were discussed with the family in 71 percent of the cases, the patient in 8 percent of the cases, and neither in 21 percent (7).

Finally, a study of patients in a community hospital (49) found that resource use, as measured by hospital charges, was reduced significantly after DNR orders were written. On average, charges for patients with DNR orders dropped $97 on the day after the DNR order was written. On subsequent days, hospital charges were, on average, $100 less per day for patients with DNR orders than for patients without DNR orders—a difference of 40 percent of median daily charges (excluding room rate) for all patients. The level of care provided for patients with DNR orders varied widely however:

> Six percent received no medical care after DNR orders, that is, they died immediately after DNR designation. Twenty-five percent received hospice-type care, including pain control, counseling from the hospital's Human Support Team, and/or psychosocial support from the nursing staff. Moderate levels of care were given to 27 percent of the patients; this type of care included the administration of antibiotics for sepsis, fever, or pneumonia and medication for a chronic condition. High levels of care characterized the treatment given to 29 percent of patients; patients with multiple medical problems receiving numerous medications were likely to fall into this group. Finally, 12 percent of patients received maximal levels of therapy after DNR designation, including renal dialysis, ventilatory assistance, hyperalimentation, major surgical procedures, and/or invasive cardiac monitoring (49).

There was no relationship between patient age and the type of care provided after the DNR designation (49).

Although the kinds of treatment provided following DNR designation vary greatly among patients, several studies indicate that the kinds of care to be provided or withheld are not usually documented by the physician in the patient's medical record. As a result, nurses and others who are caring for such patients may be confused about what treatments are to be provided (7, 25,49).

In addition, anecdotal evidence suggests that Medicare payment for hospitalization and some medical treatments is sometimes denied for patients with DNR orders. The Association of Community Cancer Centers is currently surveying its member institutions concerning any experience with Medicare payment denials for terminal patients, particularly those with DNR orders (77)

Finally, although most experts agree that other life-sustaining treatments should not be automatically withheld or withdrawn when a DNR order is written, some have questioned the meaning of a DNR order when other aggressive life-sustaining treatments are continued (49,91). In this context, it is interesting to note that data from three studies show that many hospital patients with DNR orders (27, 39, and 51 percent, respectively) left the hospital alive (7,49,73).

RESUSCITATION POLICIES IN HOSPITALS AND OTHER INSTITUTIONS

With varied and often conflicting attitudes about the role and responsibilities of the patient's physician, staff physicians, nurses, patients, and families, and, overall, about the goal of treatment itself, there has developed a need for mechanisms by which decisions about resuscitation can be made. In response to this need, some hospitals, nursing homes, and hospices have developed institutional guidelines and policies governing decisions about resuscitation. One hospital's guidelines for decisions about resuscitation are shown in figure 5-5.

One survey of hospitals in five Midwestern States found that over 60 percent either had or were in the process of developing a formal resuscitation policy. Two variables—institutional size and the presence of an ethics committee—were associated with the presence of resuscitation policies in the responding hospitals (61).

A 1986 survey conducted by the Joint Commission on Accreditation of Hospitals (JCAH) found that 57 percent of hospitals, 20 percent of nursing homes, and 43 percent of hospices responding to the survey had formal resuscitatation policies (39). Larger institutions, institutions accredited by JCAH, and institutions with an ethics committee were more likely than other institutions to have a formal resuscitation policy. One resuscition policy identified in the survey was instituted in 1969, but the great majority had been put into effect since 1983 (53).

Hospital, nursing home, and hospice resuscitation policies have become more sophisticated and systematic in the past few years. Terms such as "competent patient," "incompetent patient," and "guardian" are defined. The responsibilities of the patient, family members, physicians, nurses, and other medical personnel are clearly delineated. Even the meaning of resuscitation itself has been more specifically defined (14).

Many institutional resuscitation policies include statements about the following:

- resuscitation as a standing order, to be initiated unless there is a physician's order to the contrary;
- who may write DNR orders;
- the medical conditions that justify a DNR order;
- procedures for determining the patient's decisionmaking capacity;
- procedures for ascertaining the patient's wishes;
- the role of the family, close associates, and other persons in the decisionmaking process;
- the scope of the DNR order (e.g., a DNR order does not limit other forms of medical intervention);
- documentation of the DNR order in the patient's record;
- discussion of the DNR order with involved staff; and
- procedures for periodic review (e.g., subject to daily review, may be revoked at any time) (14,53).

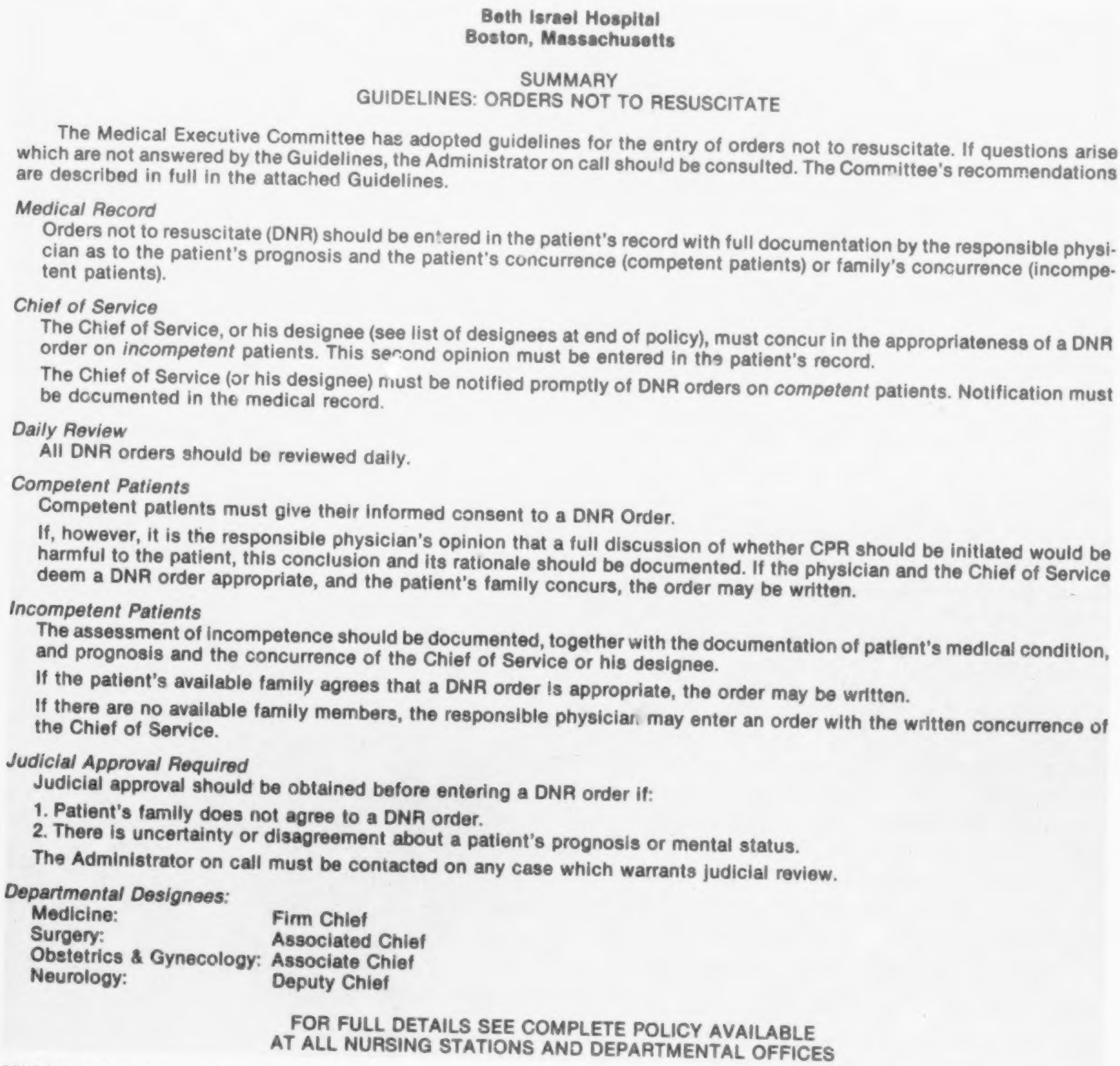
Beyond the common elements listed above, existing resuscitation policies show considerable diversity, reflecting the characteristics of different institutions.

According to the JCAH survey, the most common problems encountered by institutions in implementing resuscitation policies were conflicts between physicians and nurses about DNR orders and the need for continuing education of staff about the policy (53). A third problem reported by the institutions was the difficulty of defining the relationship between DNR orders and other treatments. This problem has been identified by many observers (25,33,60) (see also previous section on "DNR Orders and Other Life-Sustaining Treatments"). Although some facilities have developed policies to define what treatments should be provided for patients with DNR orders, most have not. The JCAH survey found that among institutions with formal resuscitation policies, only 17 percent of hospitals, 7 percent of nursing homes, and 12 percent of hospices had policies addressing the withholding or withdrawing of other treatments (53).

In general, national medical, hospital, nursing home, and hospice associations have not developed specific guidelines for institutional resuscitation policies. Some have issued general statements on the use of CPR, however. The following statement by the 1973 National Conference on Standards for Cardiopulmonary Resuscitation and Emergency Cardiac Care is an example.

> The purpose of cardiopulmonary resuscitation is the prevention of sudden, unexpected death. Cardiopulmonary resuscitation is not indicated in certain situations, such as in cases of terminal, irreversible illness where death is not unexpected or where prolonged cardiac arrest dictates the futility of resuscitation efforts. Resuscitation in these circumstances may represent a positive violation of an individual's right to die with dignity (62).

Figure 5-5.—Resuscitation Policy Adopted by One Hospital



Beth Israel Hospital
Boston, Massachusetts

SUMMARY
GUIDELINES: ORDERS NOT TO RESUSCITATE

The Medical Executive Committee has adopted guidelines for the entry of orders not to resuscitate. If questions arise which are not answered by the Guidelines, the Administrator on call should be consulted. The Committee's recommendations are described in full in the attached Guidelines.

Medical Record

Orders not to resuscitate (DNR) should be entered in the patient's record with full documentation by the responsible physician as to the patient's prognosis and the patient's concurrence (competent patients) or family's concurrence (incompetent patients).

Chief of Service

The Chief of Service, or his designee (see list of designees at end of policy), must concur in the appropriateness of a DNR order on *incompetent* patients. This second opinion must be entered in the patient's record.

The Chief of Service (or his designee) must be notified promptly of DNR orders on *competent* patients. Notification must be documented in the medical record.

Daily Review

All DNR orders should be reviewed daily.

Competent Patients

Competent patients must give their informed consent to a DNR Order.

If, however, it is the responsible physician's opinion that a full discussion of whether CPR should be initiated would be harmful to the patient, this conclusion and its rationale should be documented. If the physician and the Chief of Service deem a DNR order appropriate, and the patient's family concurs, the order may be written.

Incompetent Patients

The assessment of incompetence should be documented, together with the documentation of patient's medical condition, and prognosis and the concurrence of the Chief of Service or his designee.

If the patient's available family agrees that a DNR order is appropriate, the order may be written.

If there are no available family members, the responsible physician may enter an order with the written concurrence of the Chief of Service.

Judicial Approval Required

Judicial approval should be obtained before entering a DNR order if:

1. Patient's family does not agree to a DNR order.
2. There is uncertainty or disagreement about a patient's prognosis or mental status.

The Administrator on call must be contacted on any case which warrants judicial review.

Departmental Designees:

Medicine:	Firm Chief
Surgery:	Associated Chief
Obstetrics & Gynecology:	Associate Chief
Neurology:	Deputy Chief

FOR FULL DETAILS SEE COMPLETE POLICY AVAILABLE
AT ALL NURSING STATIONS AND DEPARTMENTAL OFFICES

SOURCE: Beth Israel Hospital, Boston, MA, Jan. 1, 1984.

In addition, many national associations support their member institutions by providing information or facilitating communication among institutions about resuscitation policies.

The VA has developed standards to guide VA facilities in formulating resuscitation policies tailored to the population they serve. The standards acknowledge that:

> . . there will be those cases where, in the exercise of sound medical judgment, a licensed physician who knows the patient may appropriately give an instruction not to institute resuscitation at the bedside of a patient who has just experienced an arrest" (83).

The most recent VA statement recognizes the variation among States in statutory and case law relevant to decisions about life-sustaining treatment and requires VA facilities to develop resuscitation policies that are consistent with both existing State law and applicable VA standards (84).

In 1983, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research recommended that "in order to be accredited, hospitals should be required to have a general policy regarding resuscitation" (69). In response to this recommendation and widespread agreement about the need for such policies, JCAH has developed a new standard for accreditation of hospitals and nursing homes that will require each institution to have a policy for decisions about resuscitation. The new JCAH standard will be implemented in 1988 (67).

The proposed JCAH standard does not require hospitals and nursing homes to address the relationship between DNR orders and other life-sustaining treatments that might be provided for the patient. Such a requirement could be a logical next step. In the meantime, national hospital and nursing home associations might encourage their member facilities to adopt institutional policies that require explicit consideration and documentation of what other treatments are to be provided or withheld once a DNR order has been written.

FINDINGS AND IMPLICATIONS

CPR involves various procedures that can be classified as either basic or advanced cardiac life support. The basic procedures, external cardiac massage and mouth-to-mouth ventilation, can be administered anywhere, by any person trained in the techniques. The more advanced procedures must be performed by trained health professionals, usually in a hospital where the equipment is readily available.

Since its development in 1960, the tremendous life-saving potential of this technology has become widely recognized, for at some point in the dying process of every person, the heart stops beating and resuscitation can be applied. Indeed, resuscitation is used for thousands of people each year, the majority of whom are elderly.

Specific data for utilization or cost of resuscitation are not available. Rough estimates indicate that 204,000 to 413,000 elderly persons may receive CPR in hospitals annually, and an additional but unknown number receive CPR in the community. Research is needed to develop accurate utilization and cost figures.

In contrast, the outcomes of resuscitation have been extensively studied. On average, one-third to one-half of resuscitation attempts in hospitals are initially successful. Among those patients who are successfully resuscitated in the hospital, one-third to one-half (about 10 to 25 percent of all those who receive CPR) initially recover enough to be discharged from the hospital.

Various complications and injuries may accompany resuscitation. The most common complications are injuries such as rib fractures, collapsed lungs, and ruptured stomachs. Some survivors suffer permanent brain damage or need mechanical ventilation, dialysis, and/or invasive hemodynamic monitoring.

Factors that influence resuscitation outcomes include the patient's underlying physical condition, the nature of the cardiac arrest, the elapsed time between cardiac arrest and initiation of resuscitative efforts, and duration of the resuscitation attempt. The patient's age alone is not a good predictor of resuscitation outcomes.

Several age-related conditions, such as osteoporosis, cataracts, arthritis, and altered metabolism, however, may increase risk of complications. Available evidence indicates that resuscitation is not performed differently with elderly patients than with younger ones. More research is needed to assess any added risks associated with age.

More is known about how decisions about resuscitation are made than about how decisions about other life-sustaining technologies are made. Although resuscitation decisions vary from individual to individual, factors that are frequently involved include the clinical indicators of the chance of success, as well as the patient's mental status. The patient's age is sometimes a factor in decisions about resuscitation, although age alone is not a good predictor of outcome.

It is now widely accepted that resuscitation is not appropriate for *every* patient. When cardiac arrest occurs unexpectedly and/or there has been no advance deliberation of the appropriateness of resuscitation, CPR is almost always attempted because the alternative for the patient is death. For patients in hospital and other settings, decisions about whether to initiate CPR are sometimes considered in advance of a patient's cardiac arrest. Although the bias towards attempting resuscitation is very strong, there is increasing use in these institutions of DNR orders—directives to withhold CPR.

Problems with DNR orders include lack of patient and family involvement in decisions about their use, lack of documentation of the orders, and disagreements among physicians, nurses, and family members about whether a particular patient should have a DNR order. In order to address these problems, some hospitals, nursing homes, and hospices have developed formal resuscitation policies, but many have not.

JCAH has recently issued new standards that require hospitals and nursing homes to develop resuscitation policies in order to be accredited. Such policies will help resolve some of the problems in existing decisionmaking procedures and may provide some legal protection for physicians, nurses, and others who adhere to them. At the least, such policies will clarify for health care professionals, patients, and families how decisions about whether to provide CPR will be made in each facility. National hospital, nursing home, and hospice associations and physicians' and nurses' associations have a role in providing expert advice and consultation to facilities and individual professionals involved in the development of institutional resuscitation policies.

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Mechanical Ventilation

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Chapter 6

Mechanical Ventilation

INTRODUCTION

Mechanical ventilation is one of the major life-support systems of the 1980s. For patients suffering severe impairment or even complete failure of respiratory function, the ventilator (or "respirator," as the device is better known) is literally the link between life and death. Its capacity to take over the vital role of the respiratory muscles, inducing rhythmic inflation and emptying of the lungs, is beyond debate. Experience with this technology provides clear evidence that, for a substantial and diagnostically diverse patient population, mechanical ventilation can effectively assist or replace normal spontaneous breathing. Its wide availability and usually safe application have enabled thousands of patients of all ages to survive life-threatening pulmonary, neuromuscular, and neurologic disorders, as well as high-risk surgical procedures.

But, like the other life-sustaining technologies considered in this report, mechanical ventilation is a mixed blessing. Its technical virtuosity and potential good are not always good enough. The ventilator has attained notoriety as the focus of ethical and legal dilemmas. For severely ill patients and their families, as well as many health professionals, decisions about the use of this technology are the source of considerable anguish. While offering hope of prolonged life, mechanical ventilation has drastic implications for the quality of that life. Furthermore, the costs associated with this technology are enormous, and the Federal Government bears a large proportion of these costs. Thus, in assessing this technology, the appropriate emphasis is not: does it work? but rather, under what circumstances is its use appropriate?

In the care of many acutely ill patients, mechanical ventilation lasting only hours or a few days is sufficient. For patients with reversible disease or injury to the chest wall and for some surgical patients, artificial ventilation can buy the time needed for definitive therapeutic interventions to take effect or for spontaneous improvement to occur. In a short time, the ventilator can be removed and normal breathing resumes. Unfortunately, however, mechanical ventilation has never been shown to improve the underlying pathology of any disease (9). Thus, acutely ill patients whose underlying disease is chronic or irreversible can become, sometimes unexpectedly, chronically *ventilator dependent*. Their continuing need for mechanical ventilation may be total, i.e., 24-hours a day, or it may be limited, i.e., only during sleep or intermittently through the day.

For patients with chronic, irreversible, or degenerative diseases or paralysis affecting respiration, mechanical ventilation represents a last resort, a sign that preventive measures or cures were ineffective or unavailable. At the same time, for such patients, this technology offers a realistic possibility for prolonged life. Thousands of patients, or others acting on their behalf, have chosen ventilator dependence as the best alternative and, with it, many have managed to develop and maintain successful family relationships and even careers.

Ventilator patients who are successfully "weaned"[1] as well as chronically ventilator-dependent persons who remain functionally able represent important technological successes. Unfortunately, however, not all individuals fall into these categories. Mortality among patients receiving mechanical ventilation is very high. Most reports have found survival of the initial hospital episode to be under 55 percent (27,75,87,98,128,129); and mortality is usually highest for elderly patients (75,83,85,87,88,95,129).

Furthermore, among those patients who become permanently ventilator dependent are some whose physical and/or mental functioning is severely and irreversibly impaired. Although patients who cannot be weaned are thought to represent fewer than 5 percent of all patients receiving mechanical ventilation (57), their care raises the most difficult issues, for health professionals, families, institutions, governments, and sometimes for themselves.

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[1] Weaning is the step-by-step removal, over a period of days, weeks, or months, of ventilatory equipment that the patient is dependent on, with restoration of adequate spontaneous respiration.

Whether a particular patient will benefit from mechanical ventilation is initially a medical judgment. Often, however, no clear diagnosis has been established, and even when one has, the patient's prognosis may remain highly uncertain. The patient and/or family members may not agree with the advice of their physician. Moreover, physicians, nurses, and other professional caregivers may not agree with each other. Thus, the decisionmaking problem moves outside of physicians' primary expertise into the realms of psychology, ethics, religion, economics, and law.

Over the 30-year history of modern ventilator technology, advances in what is technologically possible and changes in the social context have brought changes in the purposes, places, personnel for, and methods of providing care. The fo-

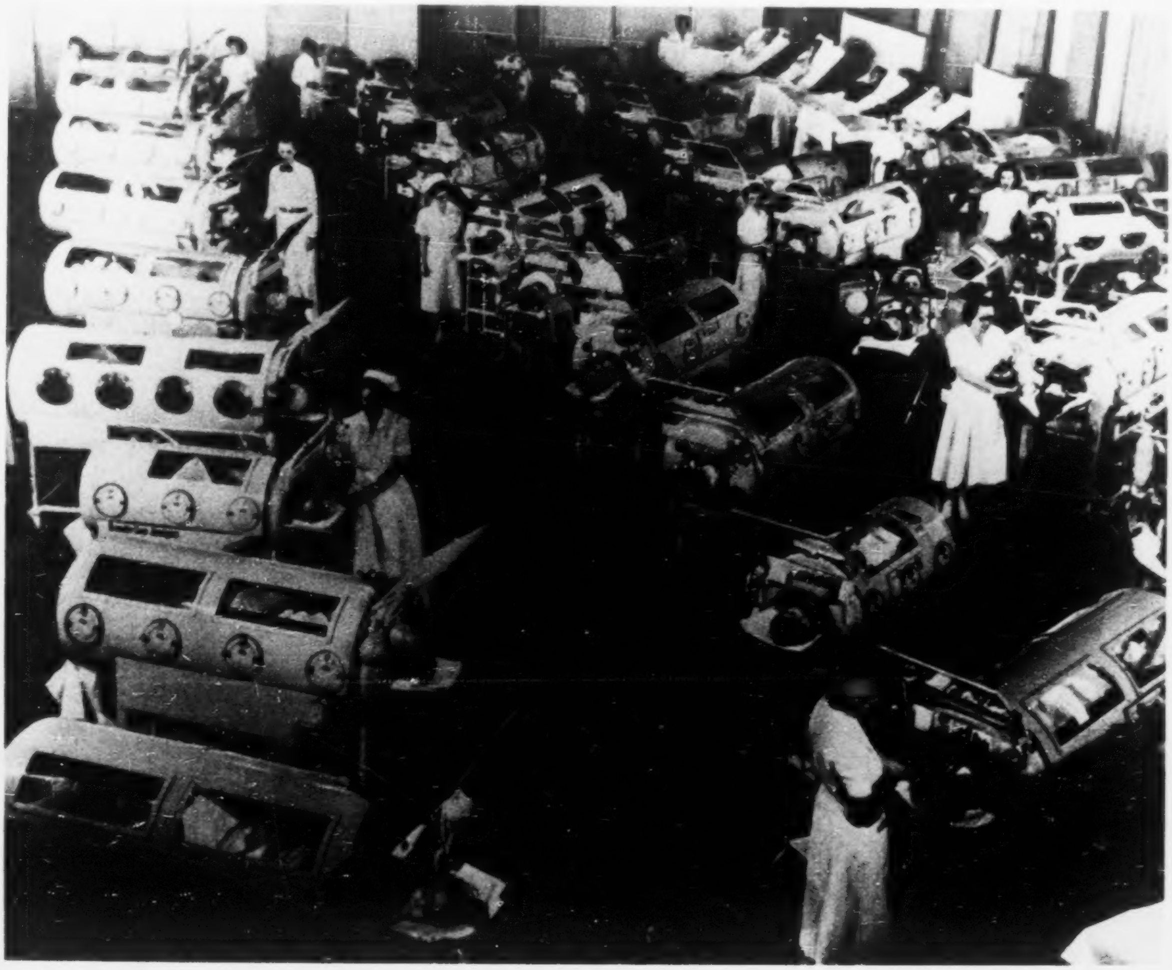

Photo credit: Warren E. Collins, Inc.

During the polio epidemic of the 1950s, iron lungs sustained thousands of lives. This is a scene from the Los Angeles County Hospital.

cus has shifted from the operating room, to long-term care, to intensive care, and, lately, back to long-term care, including home care.

Perhaps the most significant development has been the considerable expansion of the potential patient population (106). Prolonged mechanical ventilation first became a reality in the midst of the worldwide epidemics of poliomyelitis during the first half of this century. In Europe and the United States, thousands of polio victims who suffered respiratory paralysis were sustained for months or years with "iron lungs" and other early types of ventilators. Individuals who were part of this cohort of patients are distinguished from their successors by their relative good health and their *youth* at the time mechanical ventilation was instituted. These individuals and events stimulated by their plight, including the virtual eradication of polio in developed countries, continue to stand out as historical examples of medical technology at its best.

Now, however, recipients of mechanical ventilation include patients in their eighties or nineties with multiple life-threatening conditions; patients whose presumed temporary loss of spontaneous breathing proves to be permanent; patients for whom it is known in advance that spontaneous breathing will never be restored; and patients who are demented, unconscious, or even brain dead. These patients are the source of new ethical and legal issues, intensified economic strains, and heightened public interest.

This chapter examines a variety of issues pertaining to decisions about the use of mechanical ventilation. Because the issues are exaggerated with longer use, the chapter generally focuses on acute ventilation that becomes *prolonged* or *chronic*. Definition of this concept is, however, problematic. Some authors regard ventilation lasting 48 hours as "prolonged" (e.g., 27,98), while others define prolonged ventilation as that which continues for 1, 3, or even 6 months. According to some authorities, patients who require mechanical ventilation for as long as 2 weeks are essentially the same patients who require it for a month or longer (21). In general, the discussion that follows refers to individuals who have become ventilator dependent and who are unlikely to regain spontaneous respiratory function.

DESCRIPTION OF MECHANICAL VENTILATION

Respiratory Failure: The Need for Mechanical Ventilation

Respiratory failure is a life-threatening condition in which the respiratory apparatus is unable to provide adequate oxygenation (delivery of oxygen to the blood) and/or ventilation (removal of carbon dioxide from the blood). It is an unstable condition, and if untreated, further deterioration and eventual *respiratory arrest* (i.e., the complete cessation of effective breathing) are more likely than improvement (111). Respiratory failure and arrest can occur in individuals of any age. As a group, however, elderly people are at greater risk because of normal age-related declines in pulmonary function, as well as the higher prevalence of diseases associated with respiratory problems and higher prevalence of comorbidities in general.

Clinical evidence shows that, "with a normal aging process, the bronchopulmonary system should be adequate for about 90 years of continuous functioning" (78). After age 25, however, healthy individuals experience a gradual decline in pulmonary function (72). Normal changes in pulmonary function are due to aging per se; to the cumulative effect of exposure to environmental pollutants; to residual effects of disease and allergies; and to reduced levels of physical activity. Changes may occur in lung volume and in all aspects of respiratory function. Probably the single most significant risk factor affecting healthy individuals is cigarette smoking (121).

Severely impaired respiratory function and eventual respiratory failure may result from airway obstruction, inadequacy of the ventilatory muscles, lung disease, or chest injury, as well as from a variety of cardiac, neurological, and neuromuscular disorders. The most common causes—asthma and COPD—are primarily diseases of older people (see box 6-A). In addition, other conditions associated with the risk of respiratory failure, including pneumonia, sepsis, and pulmonary edema, are more likely to result in respiratory failure when the victim is elderly (111). Diagnoses associated with respiratory failure and subsequent mechanical ventilation in adults are listed in table 6-1.

Changes in pulmonary function associated with normal aging and changes due to disease are interrelated and difficult to distinguish. The confounding of normal and abnormal processes can lead to generalizations about elderly patients and to assumptions about reserve capacity that are incorrect in individual cases.

Box 6-A.—Chronic Obstructive Pulmonary Disease

COPD, also known as chronic obstructive lung disease, designates a group of diseases characterized by chronic airflow limitation, especially during expiration. Asthma, chronic bronchitis, and emphysema, as well as much less common diseases, such as bronchiectasis and cystic fibrosis, are examples. Diseases of the airway are characterized by excessive mucus secretion of the bronchorespiratory tree and chronic inflammatory changes in the small airways (in chronic bronchitis) or by abnormal enlargement of the alveoli and destructive changes in the alveolar walls, resulting in abnormal gas exchange (in emphysema). Chronic productive cough and difficulty breathing are the main manifestations. COPD is progressive and thought to be irreversible (35). If severe, hypoxemia, cor pulmonale, congestive heart failure, and eventual respiratory arrest can result.

COPD is seldom symptomatic before the age of 55 or 60 (111). An estimated 4 million Americans suffer from some form of the disease (114). In 1984, COPD, bronchitis and asthma, and pneumonia with pleurisy (diagnosis-related group (DRG) 86, 96, and 89, respectively) were among the 10 most frequent DRGs for hospital discharges (14). Closely associated with cigarette smoking and workplace chemicals (especially coal mining, asbestos, steel, and flax), emphysema is more common among men than women (35), and it is the fastest growing cause of death in the United States (30).

Treatment of COPD is directed toward reversing the abnormalities of the airway and their effects. Most patients are treated effectively with oxygen, bronchodilators, and other drugs, without resort to mechanical ventilation. As the disease progresses, however, severe ventilatory failure becomes chronic and mechanical ventilation may be the only treatment option.

Table 6-1.—Diagnoses Associated With Risk of Respiratory Failure and Subsequent Mechanical Ventilation in Adults[a]

Pulmonary diseases
- Chronic obstructive pulmonary disease (COPD)
  - Asthma
  - Bronchitis
  - Emphysema
- Chronic restrictive lung disease
- Adult respiratory distress syndrome
- Interstitial lung disease
- Acute bronchial asthma
- Pneumonia
- Pulmonary edema
- Pulmonary embolism
- Tuberculosis
- Lung cancer

Neuromuscular disorders
- Amyotrophic lateral sclerosis (ALS)
- Diaphragmatic paralysis
- Guillain-Barre syndrome
- Myasthenia gravis
- Kyphoscoliosis and senile kyphosis
- Multiple sclerosis
- Muscular dystrophy
- Poliomyelitis
- Tetanus

Neurological disorders
- Cerebrovascular accident (stroke)
- Brain trauma
- Status epilepticus
- Drug overdose, poisoning
- Coma resulting from metabolic disorders

Cardiac disorders
- Cardiogenic shock
- Cardiac arrest
- Congestive heart failure
- Severe dysrhythmias

Major surgery (with general anesthesia)

Injury, trauma
- Chest injuries, including trauma during cardiopulmonary resuscitation (CPR)
- Spinal cord injuries
- Hypothermia
- Burns, smoke inhalation

Other
- Metastatic cancer
- Aspiration

[a] Diseases associated with short- as well as long-term ventilation are included because of the potential for the former to evolve into the latter.

SOURCE: Office of Technology Assessment, 1987

The Ventilator Apparatus

The mechanical ventilators in use today range from the relatively simple and relatively inexpensive variations of machines developed in the 1920s to the highly complex and expensive state-of-the-art ventilators found in intensive care units (ICUs). The pressure gradient necessary to deliver air or a mixture of air and other gases (especially oxygen) to a patient may be produced either by *negative pressure* (i.e., below-atmospheric pressure) applied to the chest wall or by *positive pressure* (i.e., above-atmospheric pressure) applied to the airway. Frequently, ventilators are classified along this dimension.

Negative Pressure Ventilators

The first ventilators to receive wide use for patients requiring long-term ventilatory support were negative pressure devices introduced during the epidemics of paralytic poliomyelitis from 1910 to the mid-1950s. Exemplified by the iron lung, these devices were, for the most part, chambers or cabinets in which the patient was placed, from neck to toes, and enabled to breathe by the force of alternating negative and positive pressure. A major problem with these "tank" or "body respirators" is that they render the patient inaccessible for medical and nursing care. Another major problem, recognized only after the technology improved, is that the ventilation provided by negative pressure devices is inadequate for many patients. A 1978 report estimated that only 350 tank respirators remained in use in the United States (126).

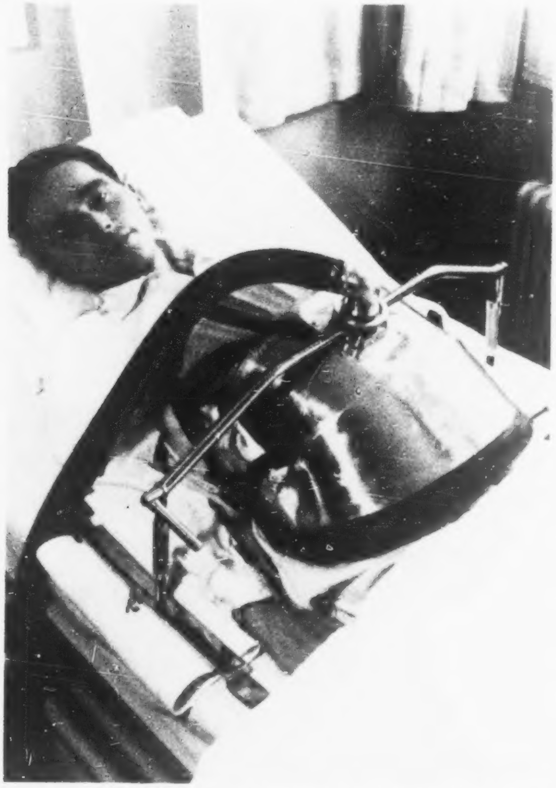

Photo credit: Courtesy of Yearbook Medical Publishers
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This patient breathes with the aid of a cuirass, the most widely used negative pressure ventilator today.

Modern negative pressure ventilators reduce the problem of access to the patient posed by the iron lung and are also more portable. The most widely used negative pressure ventilator today is the cuirass (120). This consists of a metal or plastic shell, resembling a shield, that covers the chest and/or abdomen, and that is connected by a flexible hose to a vacuum pump. Negative pressure is intermittently cycled in the space between the shell and the patient's body, causing passive excursion of the diaphragm and expansion of the lower rib cage.

Other negative pressure devices in use today include the Pulmowrap ("poncho"), the pneumobelt, and the rocking bed. The Pulmowrap is a cloth or plastic wrap that operates by the same principal as the cuirass, cycling negative pressure in the space created around the body. The pneumobelt is another wearable device that ventilates mainly the lower lobes of the lungs by its alternate inflation and deflation. The motion of the rocking bed causes passive excursion of the diaphragm and regulates both the volume of the breath and the breathing rate.

Negative pressure ventilators are used primarily in long-term care institutions and home care for medically stable patients who require ventilatory assistance less than 24 hours per day. Most of these patients have chronic respiratory insufficiency due to neuromuscular disorders, polio, or spinal cord injuries. Negative pressure devices are rarely used in acute care hospitals, but the complications associated with positive pressure ventilation and tracheostomy tubes (see "Outcomes of Mechanical Ventilation," below) have created renewed interest in negative pressure equipment for some hospitalized patients (44). Also, preliminary reports suggest that nocturnal use of negative pressure ventilators to rest the respiratory muscles is beneficial for some patients (68).

Positive Pressure Ventilators

Positive pressure ventilation has been regarded since the mid-1950s as the superior technique for acutely ill patients and for most stabilized ventilator-dependent patients. Compared with negative pressure devices, positive pressure ventilators offer several advantages. Most important, the volume and delivery rate of the inspiratory gases can be carefully controlled, and receipt of these gases by the patient is rather certain. Thus, the likelihood is greater with positive than with negative pressure devices that a patient will be *optimally* ventilated. In addition, the patient receiving positive pressure ventilation is completely accessible to caregivers.

The functioning of positive pressure ventilators involves the application of above-atmospheric pressure to the patient's airway. This produces an inspiratory driving pressure. The lung and chest wall provide elastic recoil, creating a driving pressure back up the airway. This same basic process can be accomplished by regulation of pressure, airflow, rate, or volume, and positive pressure ventilators are usually classified according to these parameters, any one of which can be preset to trigger the end of the inspiratory phase. The patient's specific condition and expected duration of need for mechanical ventilation may indicate one type of ventilator over another (71), but volume ventilators are most often chosen for long-term ventilatory support or for complex care (68).

"Hospital ventilators" all resemble the model shown in the photograph on p. 212. The bulk of the apparatus is physically removed from the patient, usually positioned at the bedside. The dials used to set the prescribed volume, rate, breathing pattern, etc., as well as the display of monitored functions are visible and accessible to the patient or the patient's attendants. State-of-the art hospital ventilators are complex, microprocessor-based units that permit continuous measurement of about a dozen patient parameters; the results may be displayed digitally, with lights, on CRT monitors (74), or may even be transmitted by computer modem and telephone lines to a remote central station (21). The monitoring system on most ventilators is tied to an alarm system. Unacceptable levels in monitored functions trigger a visible or audible alarm (74).

In the last decade, new kinds of positive pressure ventilators have been developed specifically for use outside the hospital, where portability, ease of use, and low cost are essential. These "home ventilators" are smaller and lighter than hospital ventilators, but have many of the same capabilities, including a range of volume, pressure, and breathing rates; monitoring of patient pressure and power supply; emergency alarms and standby power. Under the direction of a physician, nurse, or respiratory therapist, home ventilators can be operated by patients themselves, by family members or other nonprofessional caregivers. Some models of positive pressure home ventilators can operate on a 12-volt automobile-type battery, enabling patients to travel by wheelchair, car, or plane. Some patients can walk, carrying or pushing the ventilator on a small wagon. Stationary (or console) ventilators are also used in home care (21).[2]

Positive pressure ventilation requires a physical link between the ventilator and the patient. This physical link is accomplished by the insertion of flexible, sterile tubing leading from the ventilator into the patient's airway, through the nose, mouth, or directly into the trachea. To ensure that the patient receives the full prescribed breath and the proper proportion of oxygen, an inflatable balloon cuff at the patient's end of the tube may be used to reduce the possibility of leakage.

The method of *intubation* depends initially on the urgency of the situation, expected duration of ventilatory support, whether or not the patient is alert, medical details, and available personnel.

---

[2] Some physicians limit the use of portable ventilators to 4- to 5-hour periods or to daytime use, recommending the more reliable console machines for nighttime and when caregivers may be less available or less alert to problems (44).

Photo credit: © 1980 Springhouse Corp. Reprinted with permission.

This patient indicates her tracheostomy, the surgically created opening through which tubing for mechanical ventilation can be inserted.

Each method has distinct characteristics in terms of patient comfort, needed care, and risk of complications.

Unless the need for mechanical ventilation is certain to be prolonged, endotracheal intubation is the preferred technique. In this method, the tube is inserted through the natural opening of the trachea, either through the patient's mouth (i.e., orotracheal intubation) or through the nose (i.e., nasotracheal intubation). Because the duration of ventilation is usually difficult to predict, most patients undergo endotracheal intubation at the start of their treatment. There is some disagreement about how long endotracheal intubation can be maintained, but most sources put the limit at 1 to 2 weeks (112).

Patients requiring ventilatory support of longer duration must undergo a surgical procedure known as a *tracheotomy*, to produce an opening into the trachea, through the neck. This opening, the *tracheostomy*, allows the insertion of a tracheostomy tube. This method of intubation maximizes patient comfort and facilitates removal of secretions from the airway, via *suctioning* (71). However, tracheostomy is associated with numerous serious complications (see "Outcomes of Mechanical Ventilation," below).

All methods of intubation interrupt important natural functions of the upper airway, including the natural processes of humidification, filtration, and warming of inspired gases, and each interferes with normal cough and gag reflexes. The ventilator support system must compensate for these lost functions. A humidifier is used to prevent dryness of the respiratory mucous membrane. Filters prevent foreign material from reaching the lungs, and heat controls prevent loss of body heat. Because most ventilator patients are unable to cough effectively, suctioning is an important component of care (73).

The ventilation equipment and the patient are literally tied into a common system that must be adjusted to a perfect balance. The patient's respiratory drive, whether normal or abnormal, and the rhythm of the ventilator must be synchronized, so that "competition" or "interference" does not detract from the optimal functioning of either. The ventilator's operating *mode* denotes the degree of control the machine has over the patient's breathing. In the mode called "control ventilation," for example, the ventilator provides total support, cycling independently of the patient's breathing effort or response. This mode is used for unconscious patients and for those whose spontaneous ventilation is significantly depressed. In the acute care setting, interference from the patient sometimes is managed by the administration of heavy sedatives or paralyzing agents to permit optimal functioning of the ventilator (20).

Safety and Reliability of Ventilation Equipment

Like any mechanical device, ventilators can malfunction or fail. Problems may be due to the ventilator itself; to other components of the system, especially the tubing, oxygen supply, or power source; or to human error. Appropriately scheduled and correctly performed maintenance are essential.

Mechanical ventilators are subject to regulation by the Food and Drug Administration (FDA). FDA's Medical Device Reporting regulation, implemented in December 1984, requires manufacturers of medical devices to report any deaths or serious injuries associated with their products. Between December 1984 and March 1987, FDA received approximately 2,800 reports of problems with positive pressure mechanical ventilators (hospital and home models).[3] During the same period, FDA also received approximately 700 reports on positive pressure ventilators under the voluntary Medical Device and Laboratory Product Problem Reporting Program (100). Although fault has not been determined in all reported incidents, concern about the safety and reliability of these ventilators is understandable.

FDA has designated positive pressure ventilators for hospital and home use as Class II medical devices (i.e., devices for which general controls are deemed inadequate to ensure safety and efficacy, and for which sufficient information exists or could be developed to establish performance standards). They were among the very few Class II medical devices for which, in 1986, FDA initiated the process of developing a regulatory performance standard (17). However, FDA's invitation for offers to submit or develop a standard (51 FR 11516) brought no acceptable responses, and the agency has since withdrawn plans to develop a regulatory standard. Instead, FDA will attempt to solve the reported problems with ventilator equipment by other, less costly means (17).

Hospital ventilators used in critical care and anesthesia are subject to voluntary standards such as the performance standard developed in 1976 by the American National Standards Institute (5). That standard is currently being revised by the American Society of Testing and Materials. A standard developed by the International Standards Organization also applies to hospital ventilators (8).

The American Society of Testing and Materials, in response to numerous reported problems with home positive pressure ventilators, is also developing a voluntary performance standard for these devices. (FDA is participating in the process.) In addition, a subcommittee of the American Society of Testing and Materials has been formed to develop standards of *practice* for home ventilation (8).

Because problems with ventilation equipment may be life-threatening, whether in the hospital or elsewhere, a backup power supply (battery or generator) and backup ventilator are usually needed. Emergency equipment for resuscitation is also needed in the event that machine or power failure leads to respiratory arrest. Even in the home, a simple device for resuscitation, usually an ambu-bag (see ch. 5), should be available for

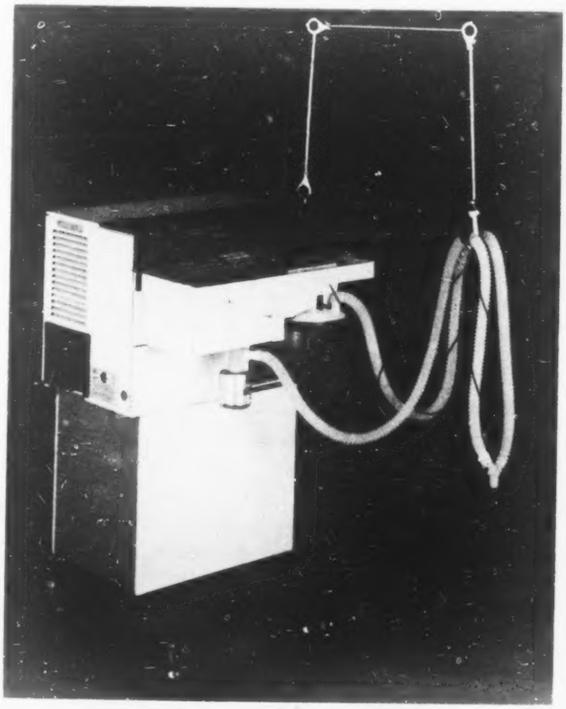

Photo credit: Puritan-Bennett Corp.

The Bennett 7200a is a microprocessor-controlled volume ventilator typical of the positive pressure ventilators used in hospitals today.

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[3] In January 1986, FDA initiated a civil suit against one major manufacturer, whose home ventilators had been linked to 7 deaths, 9 serious injuries, and as many as 663 malfunctions (28). Equipment problems, however, are not unique to any one manufacturer or model (44).

all ventilator-dependent patients. In some communities, power companies, police and fire departments maintain registries of individuals who have life-support equipment in their home, providing an additional measure of safety.

Treatment Settings

Mechanical ventilation is usually initiated in an emergency room or ICU. Many ventilator patients who have been stabilized, however, do not need to remain in an ICU and may not need to remain in the acute care hospital at all. Patients requiring long-term ventilatory support have been successfully treated in regular medical units of acute care hospitals, special step-down and rehabilitation units, chronic and rehabilitation hospitals, nursing homes, group homes, and their own homes. The various settings in which mechanical ventilation is provided imply widely different levels of care, cost, and patient responsibility, and they have considerable impact on the patient's quality of life.

Acute Care Hospitals

For patients who are medically unstable or at high risk and for whom aggressive life-sustaining treatment is desirable, the appropriate setting for the provision of mechanical ventilation is the ICU. The sophisticated equipment and skills available in the ICU, and the high staff-to-patient ratio, are needed to provide round-the-clock monitoring and care. In addition to ventilation, nutritional support, and any other treatments that may be necessary can be rapidly initiated and simultaneously managed. However, the ICU is by far the most restrictive and, almost always, the most expensive setting in which mechanical ventilation is provided.

Some ventilator patients remain in acute care hospitals long after they are medically stabilized (2). This situation may be due to the shortage of options in the community, caregivers' lack of awareness of the options, or reimbursement considerations (see below). The inappropriate use of ICU and other acute care beds increases costs, reduces the patient's quality of life, and may create a shortage of ICU beds. Moreover, some observers suggest that physicians and other health professionals who trained and practice in acute care hospitals lack the experience and special expertise required to provide good quality care to patients who are chronically ventilator dependent (21).

The feasibility of caring for a ventilator-dependent patient outside an acute care hospital depends on factors such as the patient's physiological stability, comorbidity, and mental status; complexity of the prescribed ventilator and regimen; extent of the patient's need for medical attention and nursing care; the patient's prognosis and minimum acceptable quality of life. Other major considerations are institutional policies; the existence of options in the community; admission criteria and available space in other facilities; distance of alternate facilities from family; the patient's personal financial resources; available reimbursement; and the ability of family members to provide social support.

Nursing Homes and Other Institutional Settings

Historically, very few nursing homes have accepted ventilator-dependent patients or kept patients who became dependent on this technology. The majority of physicians and institutions assumed, as many still do, that safe care of ventilator-dependent persons required staff and technological resources that are neither available nor feasible to provide in a nursing home. In the last few years, interest in containing hospital costs and in reducing length of hospital stay has given impetus to creation of special ventilator units within some skilled nursing facilities (14). Despite this change, however, the number of nursing homes that now care for ventilator-dependent patients is still small (115).

Nursing homes that do accept ventilator-dependent patients may provide long-term placement, transitional placement to permit training and preparation of patients who will eventually return home, and/or short-term respite for family caregivers. One of the first such programs in a nursing home opened in January 1983 at Care Centers of Michigan. This program offers comprehensive, long-term care for patients of all ages. Patients are said to enjoy improved quality of life, with a broader range of rehabilitative services and environmental options, at approximately half the cost of hospital care (25).

Other options for some stabilized patients who remain ventilator dependent are chronic care and rehabilitation hospitals. Nationwide, there are a few hospitals whose major mission is pulmonary rehabilitation. In these special facilities, many patients, including some elderly patients who could not be weaned in acute care hospitals, are successfully weaned from mechanical ventilation, or their dependence is reduced (21).

Demand for skilled nursing and other kinds of long-term care facilities for ventilator-dependent patients appears to exceed availability. In a national survey of hospital discharge planners, the availability of beds and need for complex services including ventilator care was identified as the second most serious barrier to nursing home placement (119). The Goldwater Memorial Hospital in New York City, with a respiratory rehabilitation program for 46 ventilator patients, has a normal waiting list of 50 to 75 ventilator-dependent patients ready to be discharged from acute care hospitals in the New York metropolitan area (21). The Oak Forest Hospital in LaGrange, Illinois, has a 25-bed ventilator ward and a waiting list of 75 (40).

The Patient's Home

Mechanical ventilation at home is a realistic option only for a minority of patients, whatever their age. To date, the number of elderly patients who have been discharged to their own homes on a ventilator is very small. However, home care is an option that deserves consideration because the potential benefits for patients and the potential cost-savings are great. Care within one's own home can provide the highest quality of life and, for some patients whose prognosis is bleak, improved quality of death. In their own homes, patients retain the maximum degree of control over their health care and other aspects of their life. Patients of all ages have made successful adaptations to ventilator dependence at home, and some observers believe the feasibility of home care is underestimated (70,103).

Clearly, however, home care of a ventilator patient is not a decision to be taken lightly. The patient's readiness to go home and the family's readiness to receive the patient must be carefully assessed; extensive planning and education of both patient and family are necessary. Resources for care outside the hospital must be identified and evaluated. Also prior to discharge from the hospital, reimbursement for home care must be assured. Problems related to financial and social support for families providing home care are severe, whatever the age of the patient. The feasibility of home care for ventilator-dependent patients who are elderly is reduced by the decreased likelihood that they have a spouse or other family members capable of meeting the considerable challenges home ventilator care presents.

Barriers to home ventilator care for patients of all ages include the fact that the equipment and techniques for management of ventilation in the home (and alternate community sites) are relatively new; many physicians are unaware of the home care option; and most medical centers lack the experienced personnel and resources to coordinate the transition from hospital to home. Still, some observers predict that the number of home ventilator patients will increase rapidly (118), and this prediction has led to expressions of concern that the acquisition of necessary skills and the establishment of support networks will not keep pace with the expanded number of patients (51, 66).

Another alternative to institutionalization, with benefits that parallel those of home care, is congregate housing. The goal is to provide residents the relative independence of a private apartment rather than the controlled environment of a bed in a hospital or nursing home. Congregate housing can be designed to provide both personal and medical support services to enhance independence and reduce costs (21).

Linkages Among Treatment Settings

Some ventilator patients are moved back and forth among the various treatment settings. Such moves are often necessitated by changes in the patient's medical condition. Thus, for example, a COPD patient may be weaned from the ventilator, or partially weaned, over and over again, necessitating transfers in and out of an ICU. Or, a patient who is at home may be transferred back to the hospital in the event of an acute episode. In other cases, the reasons for moving a patient are strictly non-medical. For example, a patient cared for at home may be moved to a nursing home or hospital because the physical, emotional, and/or financial strain of providing care has become too great for the family.

Continuity of care requires good linkages among the various treatment settings and service providers. To increase the options for ventilator patients they are ready to discharge, many hospitals are developing their own nursing homes or contracting with existing nursing homes for a certain number of beds (12). Hospitals that discharge ventilator-dependent patients to nursing homes or to their own homes must be prepared to provide ongoing and emergency service for these patients. Other necessary community resources for nonhospital care are reliable companies to lease and maintain equipment, registries of nurses, attendants and/or health aides, and financial assistance. Some observers believe that the best way to ensure good care and efficient use of resources is to provide quality-assurance and case-management through a system of regional centers of expertise like those that existed during the polio years[4] (21).

Caregivers

Ventilator patients in ICUs are in the care of a large and diverse group of highly skilled professionals that typically includes the attending and various consulting physicians, registered nurses, respiratory therapists and technicians, and dietitians. It may also include physical therapists, social workers, and others. The attending physician (who is likely to be a specialist in pulmonary medicine, anesthesiology, or critical care) has primary responsibility for determining whether or not mechanical ventilation is needed and prescribing the specific regimen. Registered nurses, often specialists in respiratory care or critical care nursing, have the most contact with the patient. If a decision about withholding or withdrawing treatment is considered, various members of the health care team may participate, along with the patient and/or family members.

For acutely ill, hospitalized ventilator patients, the staff-to-patient ratio is necessarily high. One hospital in Pittsburgh reports that its 16-bed surgical ICU has 7 physicians and 67 registered nurses (48). Staffing patterns vary in different institutions, however, and a more typical case is a 16-patient acute respiratory ward staffed by 2 physicians, 10 registered nurses, 2 practical nurses, 12 nurse aides, and a clerk (21). In the general medical unit of an acute care hospital, the ratio of staff (especially nurses) to patients is sharply reduced and the roles of various personnel are changed. Respiratory and physical therapists often have expanded roles. When weaning from the ventilator and/or discharge from the hospital can be considered, social workers, psychologists, psychiatrists, and rehabilitation experts become increasingly important.

In nursing homes and other institutions that care for stabilized ventilator patients, staffing needs are much simpler, though the needs of individual patients vary greatly. Care may be coordinated by a staff physician and the medical director, who may not be continuously available. This is the pattern at Care Centers of Michigan, where specially trained professional nurses, nurses aides, respiratory therapists, and rehabilitation assistants provide ongoing care. The ventilation unit at the nursing home has 1 professional nurse and 1 respiratory therapist for every 6 patients (24).

In the patient's home, there is substantial reliance on the ability of family members and the patient to provide basic care and to perform routine procedures. Respiratory therapists, nurses, aides, and attendants—under the auspices of hospitals, home care equipment companies, nursing homes, and home health care agencies—can be enlisted to assist the primary caregiver. Home care of ventilator patients raises important questions about the training and supervision of family members and other lay caregivers. Within some centers of expertise, model programs have been developed for patient and family education (39).

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[4] Regional centers of expertise were established in this country to provide comprehensive services to polio victims who required ventilatory support. As the incidence of polio fell, most of these centers closed. In France and England, comprehensive government-funded programs currently provide a full range of services, including acute care hospitals, intermediate care facilities and organizations to provide service, equipment, and personnel in the home. These programs provide needed care, care-monitoring and quality-assurance, as well as cost savings via mass purchasing (21,42,43).

UTILIZATION AND COST OF MECHANICAL VENTILATION

Utilization of Mechanical Ventilation

Available data on the utilization of mechanical ventilation are highly inadequate. Health statistics maintained and published by Federal agencies, notably the Health Care Financing Administration (HCFA) and the National Center for Health Statistics (NCHS), include no overall estimates for this technology. Moreover, the coding systems on which Federal data are based would make technology-specific analyses difficult to do and difficult to interpret.[5]

Other potential sources of information regarding the utilization of mechanical ventilation are the manufacturers and the providers of equipment and/or services for home ventilation. A survey of over 50 national organizations concerned with health care, aging, home care, health care financing, or respiratory diseases found that equipment vendors and home health care providers were the only organizations that maintained any information about the utilization or cost of mechanical ventilation (21). Unfortunately, data from private companies are generally regarded as proprietary. In addition, the markets they describe are scattered and overlapping.

Table 6-2 presents estimates of long-term ventilator utilization nationwide, from all available sources. Data from a survey conducted for OTA in 1985, under contract to Care for Life (21), are the closest thing available to national primary data on the utilization of long-term mechanical ventilation. The researchers attempted to collect data on all individuals who were receiving mechanical ventilation during a specified week and who had been ventilator dependent for more than 14 days. Data were obtained for 37 States,[6] by their respective representatives to the American Association for Respiratory Care (AARC).[7] A total of 3,771 long-term ventilator patients of all ages were found in these States. About one-third (1,236) of these individuals were over the age of 65. Based

Table 6-2.—Estimated Utilization of Long-Term Mechanical Ventilation Nationwide

	Total number of patients	Hospital patients	Home care patients	Other patients
AARC	Min 3,771[a] incl 1,236 over age 65	2,379[a] (63%)	1,279[a,b] (34%)	113[a] (3%)
Mass Thoracic Soc & Am Lung Assoc of Mass	6,575[c] incl 2,200 over age 70	4,077 (62%)	920 (14%)	1,578 (24%)
Travenol	N A [d]	N A	5,500	N A
CBO	N A	N A	4,000	N A
Sivak	N A	N A	2,500 to 4,000	N A

[a] Patients identified in the 37 States responding to AARC survey as reported by Care for Life (see text for identification of 37 States)

[b] In this study the estimate of home ventilator patients includes patients in nursing homes as well as the patient's home

[c] This is a nationwide projection based on data collected in Massachusetts (see text for discussion)

[d] N A — Not available

SOURCES **AARC** AARC survey reported in Care for Life "Prolonged Mechanical Ventilation" prepared for the Office of Technology Assessment U S Congress Washington DC 1985 **Massachusetts Thoracic Society and American Lung Association of Massachusetts** reported in B Make S Dayno and P Gertman "Prevalence of Chronic Ventilator Dependency" *American Review of Respiratory Diseases* part 2 April 1986 **Travenol** J L Retel Manager of Marketing Travenol Deerfield IL personal communication Dec 4 1985 **CBO** Congressional Budget Office U S Congress Cost estimate for draft legislation regarding Medicare and Medicare coverage for certain ventilator-dependent patients communicated in letter from R B Penner to Senator Robert Packwood Committee on Finance Washington DC Aug 13 1984 **Sivak** E D Sivak "Long Term Ventilation Where Are We Going?" presented at a postgraduate course at Rancho Los Amigos Hospital Downey CA May 1985 on the combined elderly populations of the responding States, the researchers estimated that nationally the prevalence of ventilator dependency in the elderly is approximately 5.3 per 100,000 elderly persons. (However, regional differences were also noted.)

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[5] There is currently no single DRG for mechanical ventilation but, instead, approximately 30 different DRGs that are sometimes, but not always, associated with this technology. (However, creation of two new DRGs for cases involving mechanical ventilation is proposed in HCFA's 1988 prospective payment classification changes (113).) Thus, one cannot use HCFA's data for Medicare Part A (hospital insurance) to deduce either the number of patients who receive mechanical ventilation or the associated costs. Data on procedures pertinent to mechanical ventilation, e.g., tracheotomy, endotracheal intubation, and continuous positive pressure ventilation, are coded in claims for Medicare Part B (Supplementary Medical Insurance) and these can be extracted from HCFA records. However, such data would yield very misleading estimates of the numbers of ventilator patients because the specificity of procedure codes and HCFA's requirement to code only the principal procedure (with up to two additional surgical procedures) result in a mismatch between the number of patients who have a relevant procedure and those who receive mechanical ventilation. To use the procedure codes for estimating utilization and cost would omit patients who do not have Part B insurance and double-count many who do. Similarly, procedure codes used by NCHS in its regular surveys of hospital discharges would produce a combination of double-counting and undercounting that could not be sorted out.

[6] The 37 States providing data were: Alabama, Arizona, Arkansas, California, Connecticut, Florida, Indiana, Iowa, Kansas, Kentucky, Massachusetts, Maryland/DC, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

[7] Prior to 1985, the name of this organization was American Association for Respiratory Therapy (AART).

Illustrative statewide data on ventilator use come from a 1983 study conducted by the Massachusetts Thoracic Society and the American Lung Association of Massachusetts. Surveying all institutions serving ventilator-dependent patients in Massachusetts, the researchers estimated that a total of 162 persons in the State required positive pressure ventilation for 3 weeks or longer. This is equivalent to a statewide prevalence rate of 2.8 ventilator-dependent persons of all ages per 100,000 population. Approximately one-third of the 162 ventilator-dependent patients were under age 54, one-third were age 54 to 69, and one-third were age 70 or older. If the same total rate and age distribution were assumed to exist nationwide, there would be approximately 6,575 ventilator-dependent persons in the United States (69), including approximately 2,200 persons over age 70.

Estimates from other sources suggest that the utilization of long-term ventilation may be much higher. Travenol Laboratories told OTA, based on experience of its home respiratory program for the first part of 1985, that there were approximately 5,500 ventilator users, of all ages, nationwide in *nonhospital settings alone* (i.e., nursing homes, group homes, and patients' homes) (93). (The apparent discrepancy between the AARC survey and Travenol's data is at least partially explained by the fact that Travenol's data depict utilization over a longer data collection period.) Similarly, the Congressional Budget Office (CBO) estimated that in 1984 there were approximately 4,000 Americans of all ages at home on ventilators (118). CBO's estimate is not inconsistent with an independent estimate that there are between 2,500 and 4,000 ventilator-dependent persons at home nationwide (101).

In interpreting data on the utilization of mechanical ventilation, it is important to recognize the distinction between incidence data (i.e., data related to the frequency of *new* cases in a defined population in a specified time period), and prevalence data (i.e., data related to the number of cases existing in a defined population at a given time). Each of the figures reported in table 6-2 describes the prevalence of ventilator use at the time the data were collected. Patients who recovered or died previous to the data collection and those who required ventilatory support subsequent to that time are not counted. In other words, the number of patients and other persons affected are considerably higher than these data suggest.

One point on which all available sources of data agree is that utilization rates are higher for elderly people than for the population as a whole. Since the prevalence of most conditions leading to respiratory failure increases with age, this is what one would expect.

Estimates of the proportion of ventilator-dependent patients who are elderly and in various treatment settings are shown in table 6-3. Although the figures are incomplete, they suggest that elderly individuals constitute a very large share (43 percent) of all patients who are ventilated long-term in hospitals and a smaller proportion of patients in nonhospital settings. For home care, estimates of the proportion of patients who are over 65 range from 17 to 33 percent. The high estimate is based on CBO's report that one-third of all home ventilator patients were eligible for Medicare (118). The intermediate estimate that 27 percent of home ventilator patients are 65 or older is from Travenol (93). The low estimate is from the 37-State survey reported by Care for Life (21). Only 17 percent (220) of all non-hospitalized ventilator patients in that survey were age 65 or older (see table 6-4).

Table 6-3.—Estimated Percentage of Ventilator Patients Who Are Elderly, by Setting

	Hospital	Nursing home	Home
AARC	43%	N.A.[a]	17%[a]
Travenol	N.A.[b]	N.A.	27%
CBO	N.A.	N.A.	33%

[a] In this study, the estimate of home ventilator patients includes patients in nursing homes, as well as the patient's home.

[b] N.A. = Not available

SOURCES: **AARC:** AARC survey reported in Care for Life, "Prolonged Mechanical Ventilation," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1985. **Travenol:** J.L. Retel, Manager of Marketing, Travenol, Deerfield, IL, personal communication, Dec. 4, 1985. **CBO:** Congressional Budget Office, U.S. Congress, Cost estimate for draft legislation regarding Medicare and Medicare coverage for certain ventilator-dependent patients, communicated in letter from R.B. Penner to Senator Robert Packwood, Committee on Finance, Washington, DC, Aug. 13, 1984.

Table 6-4.—Distribution of Long-Term Ventilator Patients by Age and Setting for 37 States[a]

Age	Hospital		Home		Other setting		All settings combined
	Number	Percent	Number	Percent	Number	Percent	
Under 18	445	19%	245	19%	N.A.[b]	N.A.	690
18 to 64	916	38	787	62	N.A.	N.A.	1,703
65 and older	1,016	43	220	17	N.A.	N.A.	1,236
Age not determined	2	0	27	2	113	100%	142
All ages combined	2,379	100%	1,279	100%	113	100%	3,771

[a] Alabama, Arizona, Arkansas, California, Connecticut, Florida, Indiana, Iowa, Kansas, Kentucky, Massachusetts, Maryland/DC, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Caroline, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin

[b] N.A. = Not available

SOURCE: AARC survey in 37 States, reported in Care for Life, "Prolonged Mechanical Ventilation," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1985

Table 6-4 provides more detail about treatment settings for ventilator patients of different ages. While these data describe patients in only 37 States, and the age breaks are crude, they are the most complete available data of this type. The figures clearly show that, in contrast to children under age 18 and adults ages 18 to 64, more older persons receive mechanical ventilation and more of them are treated in hospitals.

Indicators of the duration of mechanical ventilation come from a survey of institutions and two case studies conducted for OTA by Care for Life (21). Eleven hospitals across the United States and Canada* supplied data for all current elderly patients who had been treated with mechanical ventilation for at least 14 days and for at least 4 hours per day. Almost one-third of the elderly patients in those institutions had been ventilated for more than 6 months, and most of those had been ventilated for more than a year. Case studies of ventilator-dependent patients in hospitals, nursing homes, and rehabilitation institutes in Chicago and in New York City found, similarly, that between 25 and 40 percent of the elderly patients who required mechanical ventilation for at least 2 weeks needed treatment for 6 months or longer. In New York, one-third of the patients had been ventilated for 21 to 30 days and 20 percent for 30 to 90 days.

Cost of Mechanical Ventilation

Information about the cost of maintaining a patient on a ventilator comes mostly from the reports of individual hospitals and other providers describing cost experience for the patients they serve. The dissimilar requirements of different patients, the nonrepresentative samples, and other methodological problems account for considerable variation in reported costs. For all these reasons, generalizations about cost and comparisons of alternate cost estimates must be made very cautiously.

There is considerable confusion in the literature regarding how to define the cost of mechanical ventilation and, especially, *whose costs* are at issue. Distinctions are seldom made among "costs," "expenditures," and "charges," i.e., costs incurred by the hospital or other provider, paid by the insurer or patient, and billed by the provider. Many studies label as "cost" whatever dollar figures were available.

For hospitalized patients, the cost of mechanical ventilation may be defined narrowly as the costs specifically associated with ventilator care, or it may be defined broadly to include other costs associated with treatment (notably, the hospital daily rate). Similarly, for home care patients, cost may be defined narrowly as only the costs for ventilation equipment and professional services, or it may be defined to include costs of supportive equipment and services (e.g., backup equipment, wheelchairs, architectural modifications, and the services of attendants, drivers, and housekeepers). Lost income or productivity of the ventilator patient or, more likely in the case of elderly patients, family caregivers, has not been computed in any published cost estimates, but this is often a significant component of the family's cost experience.

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*The institutions surveyed were: Boston University Hospital (Boston, MA); Gaylord Hospital (Wallingford, CT); Meriden-Wallingford Hospital (Wallingford, CT); Goldwater Memorial Hospital (New York, NY); Bethesda Lutheran Hospital (Minneapolis, MN); Rancho Los Amigos (Downey, CA); Creighton University Hospital (Omaha, NE); Texas Institute for Research and Rehabilitation (Houston, TX); Emory University Hospital (Atlanta, GA); University of Wisconsin Hospital (Madison, WI); and St. Michael's Hospital (Toronto, Ontario).

Charges for Mechanical Ventilation in the Hospital

A 1983 survey by the AARC (2) found the average annual hospital charge for a ventilator-dependent patient (based on the mean daily hospital charge for respiratory plus nonrespiratory care) to be $270,830 (equivalent to $22,569 per month or $742 per day). Data from the AARC's 1985 survey reported by Care for Life (21) indicate that the average annual hospital charge had risen 11 percent to $300,760 (equivalent to $25,063 per month or $853 per day). As shown in table 6-5, published monthly hospital charges ranged from $12,300 in 1975 to $32,800 in 1982. In the surgical ICU of Pittsburgh's Presbyterian-University Hospital, the charges for critically ill ventilator patients currently exceed $2,000 per *day* (48). This includes all care in the surgical ICU except fees charged by private physicians.

In addition to the major costs associated with high staff-to-patient ratios and inpatient care in general, hospital charges reflect the high capital costs associated with mechanical ventilation. The most popular ventilators in the hospital market ranged in price, in 1984, from approximately $15,000 to $18,000 per unit (13). Expensive accessories needed to provide mechanical ventilation in the hospital include oxygen delivery systems and concentrators, blood gas monitors, and pulmonary analysis equipment.

Charges for Mechanical Ventilation in the Patient's Home

Presumed economy is one of the main reasons for current interest in home ventilator care; however, there is considerable variation and disagreement regarding home care charges. AARC's 1985 data indicate that charges for home ventilator care averaged $1,853 per month ($22,236 per patient per year) (21). Other investigators have reported monthly bills for home ventilation as low as $350 per month (for a patient requiring a ventilator only at night) (34) to over $16,000 per month (for patients requiring continuous ventilation, oxygen, and round-the-clock care by registered nurses) (108). Costs tend to be highest when the patient is first sent home, particularly if equipment is purchased.

Whether home care for ventilator patients is more economical than care in the hospital or nursing home, and the magnitude of potential savings, depends on characteristics of the particular case. The type of ventilator required, whether the equipment is purchased or rented, the amount of oxygen required, and method of oxygen delivery are key factors. Most important is the ability of the patient or family members to provide care versus the need for professional nursing services.

Table 6-5.—Reported Monthly Charges for Hospitalized Ventilator Patients

	Date	Location	No. of patients	Patient's ages	Charges[a]
Davis, et al.	1975-76	St. Louis, MO	100	Avg. 67	$12,300
Sivak, et al.	1978	Cleveland, OH	N.A.[b]	N.A.	$15,600
Feldman & Tuteur	1981	St. Louis, MO	2	Avg. 57	$17,500
Splaingard, et al.	1982	Houston, TX	N.A.	N.A.	$15,000
Banaszak, et al.	N.A.	Milwaukee, Wi	2	Avg. 61	$15,469
Giovannoni	1982	Madison, WI	5	N.A.	$32,800
AARC	1985	37 States	3,771	All	$25,063

[a] Reported charges are not adjusted for inflation.

[b] N.A. = Not available.

SOURCES: 1. H.D. Davis, III, S.S. Lefrak, D. Miller, et al., "Prolonged Mechanically Assisted Ventilation: An Analysis of Outcome and Charges," *Journal of the American Medical Association* 243(1):43-45, 1980.
2. E.D. Sivak, E.M. Cordasco, W.T. Gipson, et al., "Clinical Considerations in the Implementation of Home Care Ventilation: Observations in 24 Patients," *Cleveland Clinic Quarterly* 50:219-225, summer 1983.
3. J. Feldman, and P.G. Tuteur, "Mechanical Ventilation: From Hospital Intensive Care to Home," *Heart and Lung* 11(2):162-165, 1982.
4. M.L. Splaingard, R.C. Frates, Jr., G.M. Harrison, et al., "Home Positive Pressure Ventilation: Twenty Years Experience," *Chest* 84:376-382, 1983.
5. E.F. Banaszak, H. Travers, M. Frazier, et al., "Home Ventilator Care," *Respiratory Care* 26(12):1262-1268, 1981.
6. R. Giovannoni, "Chronic Ventilator Care: From Hospital to Home," *Respiratory Therapy* 14:29-33, 1984.
7. AARC survey in 37 States, reported in Care for Life, "Prolonged Mechanical Ventilation," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1985.

The total cost of initial purchases necessary for a home ventilator program, in 1984, has been estimated to range from $8,000 to $15,000 (41,77). Prices for popular home ventilators in 1985 were between $5,000 and $7,000. Patient circuits, hoses, valves, filters, and other needed accessories ranged in price from about $5 for a 4-inch tapered flextube to $650 for a humidifier (64). Other essential supplies, such as sterilizing agents, sold for $1.25 to $9.00 per month (79). Home ventilator patients usually must keep on hand at least a 1-month inventory of essential supplies and spare parts for their equipment (68). When equipment is rented, charges for equipment and disposable supplies range from about $825 to almost $3,600 per month, averaging $1,500 (93).

Another major expense for home ventilator patients is for extra equipment—needed as backup in the event of equipment failure; for portability; and to provide the different kinds of ventilatory support that may be needed in different circumstances (55,86). For the estimated 2,500 home respiratory patients in the United States in 1978, there were approximately 5,000 pieces of equipment in use (126). The equipment needs of one home ventilator patient are illustrated by the following comment:

> In 1949, when a sophomore in high school, I was completely paralyzed from polio and placed in an iron lung. . . . Now . . . I use, during a 24-hour period, a rocking bed and a pneumobelt powered by a Bantam portable respirator for sitting in a wheelchair. When in bed but not rocking, I use a Zephyr positive pressure blower, complete with cascade, via long hose and mouthpiece. In addition, I use emergency and maintenance frog breathing[9] and have an extra Bantam portable for traveling (125).

For home care patients, charges for regular maintenance and repair of ventilation equipment may also be significant. For rented equipment, the cost of maintenance and repair is included in the monthly rental rate, and service is the responsibility of the vendor. For purchased equipment in the home, patients are responsible for repair and maintenance, which can amount to anywhere from $1,500 to $2,500 per year (93). Some patients who use negative pressure ventilators, or their caregivers, can perform maintenance and repairs themselves, finding that "the average [negative pressure] home respirator is no more complicated than a washing machine" (26). With positive pressure ventilators, however, especially as those manufactured for home use have become increasingly sophisticated (44), self-maintenance is usually not feasible (102).

Securing and paying for proper equipment maintenance are significant problems for some home ventilator patients. Reimbursement provisions (under Medicare and private insurance) generally do not consider required maintenance, some durable medical equipment dealers are not trained to service the devices they distribute, and most repairs and recalls necessitate sending the ventilator to the manufacturer in order to maintain the warranty and prevent liability (44).

Reimbursement for Mechanical Ventilation

Reimbursement for Hospital Care

Under Medicare's Part A prospective payment system (see ch. 2), Medicare pays hospitals a fixed amount that depends on the patient's DRG, rather than on the number or type of services he or she receives. Since approximately 30 DRGs are potentially associated with mechanical ventilation, and the patient may or may not qualify as an "outlier," Medicare payments for ventilator patients vary widely. Often, hospital costs substantially exceed Medicare's payment for patients requiring long-term mechanical ventilation (127). This is particularly likely if the hospital stay is very long or if treatment includes a long stay in the ICU (18). Medicare will not reimburse hospitals for "administratively necessary days" (i.e., days during which inpatient care is no longer necessary but lower level care is not immediately available) unless the patient is already an outlier based on length of stay (53).

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[9] "Frog" or glossopharyngeal breathing is a substitute method of breathing that can produce adequate ventilation for short periods, even when there is total paralysis of the respiratory muscles. It uses the tongue and pharyngeal muscles to force air by repeated swallowing into the trachea and lungs. The muscles of the tongue, soft palate, fauces, pharynx, and larynx must be functional, and considerable instruction and practice are needed to learn this technique. Frog breathing may be used for emergencies, transference, chest stretching and coughing, and to permit time off the ventilator (63).

At the same time, elderly patients who require prolonged mechanical ventilation may exhaust their Medicare hospital benefits for a given episode, and they may exhaust their lifetime benefits as well. Moreover, a patient's personal obligation toward the cost of care (a deductible per admission, a portion of the daily rate for days 61 through 90, and a portion of the daily rate for each day of the 60 day maximum lifetime benefit) may exceed his or her personal or family resources. For some ventilator patients, total bills are lower at home than they would be in the hospital, but the patient's out-of-pocket expenses may remain very high and, indeed, may be higher than the unreimbursed components of hospital care. Elderly patients who deplete their personal resources or whose income is below specified limits may qualify for benefits simultaneously from Medicare and Medicaid. Medicare policy allows hospitals to bill other payers, including Medicaid, for services Medicare does not cover.[10]

CBO (117) estimated that in fiscal year 1985, combined Federal and State Medicaid expenditures for a hospitalized ventilator-dependent patient (of unspecified age) averaged $98,000 per year (equivalent to $8,167 per month or $268 per day), not including additional payments for physician charges (118).

Reimbursement for Nursing Home Care

Medicare coverage in skilled nursing facilities, for patients who qualify, is limited to 100 days. Individual nursing homes have tried, so far unsuccessfully, to work out special agreements with Medicare for more flexible reimbursement for ventilator-dependent patients (24).

Some ventilator-dependent patients require "subacute" care (i.e., care that is less intense than that provided in a hospital but more intense than that typically provided in a nursing home). Medicare and Federal Medicaid legislation do not provide subacute care benefits, however, approximately one-third of States' Medicaid programs now include provisions to address these higher costs. Under Wisconsin's "Skilled Care Reimbursement Supplement" and Illinois' "Exceptional Nursing Care" provision, for example, ventilator-dependent patients in those States are now eligible for supplemental Medicaid funds. In both, because the number of patients applying for these benefits is still very small, the rates have been negotiated by nursing homes on an individual basis (40). Some States, California for example, have provisions for extra skilled care based on preset rates (53). Some observers are concerned that even when this reimbursement is available, the rates may be too low to permit adequate staffing and quality of care (44).

Reimbursement for Home Care

Third-party reimbursement for respiratory care in the home is partial and undependable. Medicare and major for-profit health insurance companies have approved reimbursement in individual cases, (89) but the patient's out-of-pocket expenses often remain high.

Many chronic ventilator-dependent patients qualify for Medicaid, but the regular Medicaid programs of most States cover few of the expensive services (e.g., daily nursing) many of these patients need. The home and community-based waiver gives States the option to offer (but most do not) some special services to subgroups of their Medicaid patients, including ventilator-dependent patients. Under the waiver, Medicaid will cover care in the home so long as the average per capita expenditure does not exceed that for institutional care (92).

The 1985 Consolidated Omnibus Budget Reconciliation Act (COBRA, Sec. 9504) made respiratory care services for ventilator-dependent individuals an option that States can offer under their regular Medicaid programs. States can choose to extend this coverage to those patients who require mechanical ventilation at least 6 hours per day, were ventilated at least 30 consecutive days in a hospital or other institution, would need to remain institutionalized if home respiratory care were not reimbursed and would have been eligible for Medicaid inpatient benefits, want to go home, and have adequate social support services to do so.[11]

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[10] For patients who are eligible for both Medicare and Medicaid, some hospitals have sought payment for "administratively necessary days" from Medicaid, under Medicaid provisions for subacute care. In most States, these attempts have been unsuccessful, but they illustrate the confusion regarding responsibility for payment (53).

Under the provisions of Medicare Part B (Supplementary Medical Insurance), durable medical equipment (DME) is covered in the home when it is supplied directly by a DME vendor. Medicare pays 80 percent of reasonable charges, and the remaining 20 percent is the patient's responsibility. Prior to changes in Medicare regulations that went into effect in February 1985, almost all durable medical equipment for mechanical ventilation was rented. Medicare currently requires purchase of all items costing less than $120 and provides a purchase option for more expensive equipment whose expected rental cost over time would exceed the purchase price.

Effect of Reimbursement on Choice of Treatment Setting

For at least some ventilator patients, the availability or lack of reimbursement is a major influence on the choice of treatment setting. At times, the setting whose use is encouraged by reimbursement policy is not the most economical or the least restrictive. According to a representative of AARC,

Photo credit: Foster Medical Corp

Some elderly patients make successful adjustment to chronic ventilator dependence. Supportive family members and caregivers are essential.

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[11] There had been several earlier proposals in Congress to extend respiratory care services to the home. The "ventilator bills" proposed in 1985 (H.R. 2703 and S. 1249) would have provided mandatory coverage under both Medicaid and Medicare. Supporters of these bills projected annual savings of $20 million to Medicaid and no increase to Medicare (3). In contrast, CBO estimated that these provisions would be cost neutral for Medicaid but add $18 million to Medicare costs in fiscal year 1986, largely due to the projected number of new elderly patients (117).

"there are literally hundreds of people—young and old—around the nation who are needlessly confined to their hospital beds by current reimbursement policy" (2). Based on their 1985 survey, AARC reports that 34 percent (813) of all hospitalized chronic ventilator patients identified in 37 States, including 349 ventilator patients over age 65, would have been able to leave the hospital if reimbursement had been available for ventilator support in the home (21). In addition, some home ventilator patients have had to return to the hospital in order to reduce their out-of-pocket costs (21). The hospitalization of ventilator patients who could be safely cared for at home, AARC argues, not only subjects patients to unnecessary institutionalization, but also wastes up to $278,524 per patient per year, much of which is taxpayers' money.[12]

The availability and level of reimbursement also affects health care institutions' capacity to provide care. Hospitals facing high unrecoverable costs under Medicare's prospective payment system have strong incentives to limit access to ICUs, to discharge patients earlier, or to transfer patients to other facilities. Some observers fear that community, acute care hospitals will no longer be willing or able to care for Medicare patients who require prolonged mechanical ventilation (127). Also, acute care hospitals' incentives to discharge patients earlier increase the pressure on other kinds of facilities to admit them. Currently, available reimbursement for nursing homes provides only limited incentive to develop facilities for ventilator-dependent patients (115).

In States where Medicaid reimbursement is available, nursing home care is now a real alternative for ventilator-dependent patients. In some cases, however, this development has unwanted results. In at least one case in Illinois, a family was forced to move a ventilator-dependent child from *home* to a nursing home in order to reduce the cost to Medicaid (44).

CBO estimated that if coverage for respiratory therapy were available in the home, an additional 200 elderly COPD patients would be discharged home with a ventilator each year (117). Some observers caution that extending coverage for home care would give impetus to the use of mechanical ventilation for new categories of patients and could lead to a repeat of the "Pandora's box" phenomenon exemplified by Medicare's End-Stage Renal Disease program (see ch. 7). Those who dismiss this warning argue that no change in reimbursement will change the medical indications for home mechanical ventilation. Moreover, the American College of Chest Physicians' clinical guidelines for home care indicate that most COPD patients, because of the complex medical management they require, are unlikely candidates for long-term mechanical ventilation at home (44,86,102).

OUTCOMES OF MECHANICAL VENTILATION

The outcomes of mechanical ventilation reflect the wide variability in patients' physiological reserve, mental capacity, social resources, and will. Across and within each age group, patients' life expectancy and ability to cope with this technology vary greatly and often cannot be predicted. The following cases illustrate the extremes of patients and outcomes:

Senator Jacob Javits was told he had amyotrophic lateral sclerosis (ALS) in 1979, at age 75. Within 2 years, the progressive muscle weakness had confined the avid tennis player to a wheelchair; then an episode of pneumonia and respiratory failure necessitated a tracheostomy for the initiation of mechanical ventilation. Thanks to excellent health care, a supportive family, and a portable ventilator, he was able to return to his own home. For 2 years, he maintained a busy teaching and lecturing schedule,[13] then returned to an active private law practice, making frequent trips around the country and numerous public appear-

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[12] This figure represents the difference between annual hospital charges ($300,760) and annual home care charges ($22,236). Although this calculation probably overstates the potential savings to payers by assuming that hospital charges are fully reimbursed, the potential savings do appear to be substantial (21).

[13] **Unlike victims of the more serious (i.e., bulbar) form of ALS, which attacks the muscles responsible for swallowing, speech, and breathing, Senator Javits retained his ability to speak (54).**

ances. Despite his physical deterioration, his intellect and his will to live were undiminished. Near total paralysis necessitated round-the-clock nursing and assistance in virtually all physical activities. Still, he remained energetic and outspoken, trying to set an example for less fortunate patients and advocating more funding for medical research. Until his death at age 81, Senator Jacob Javits continued to serve as an effective public citizen, claiming he was "too busy to despair" (54).

A 72-year-old man with multiple myeloma and prostate cancer suffered a cardiac arrest while at his local bank. Cardiopulmonary resuscitation (CPR) was not begun until the rescue squad arrived some 10 to 12 minutes later. Finding no pulse or respirations, they provided CPR during the 8-minute ambulance ride back to the nearest hospital. In the emergency room, he was pulseless and apneic. Resuscitation was nevertheless successful, and he was transferred to the coronary care unit. There he was maintained on mechanical ventilation. He appeared to have severe anoxic brain damage, and exhibited no spontaneous neurological activity over the next 24 hours. On the 10th day, the family came forward with the request that he receive nutritional support. Although the nutritional support consultant believed it was not appropriate, nutritional support was started at the family's insistence. During the patient's subsequent rocky course, he never showed signs of cortical functioning. He died in the eighth week of hospitalization (109).

Because most causes of respiratory failure are either short-term and treatable or have a rapidly terminal course (7), most reports in the literature measure the outcomes of mechanical ventilation in the general terms of survival or, conversely, mortality. Few reports differentiate survival with successful weaning from survival with chronic ventilator dependence. The studies that have examined age-related differences in survival are few, and the studies that have focused on the social and psychological impact of prolonged mechanical ventilation describe, for the most part, younger patients or exceptional elderly patients who can return to their own homes. Prospective, randomized, controlled studies to test the outcomes of mechanical ventilation have not been performed, nor would they be ethically feasible (21).

Clinical Outcomes of Mechanical Ventilation

Survival of Respiratory Failure

There are serious problems in comparing survival data from available studies. None of the reported studies is based on a representative sample of ventilator patients, much less a representative sample of *elderly* ventilator patients. Rather, each of the available studies was conducted at a single hospital, with a unique patient population, resources, criteria for admission to the ICU, and criteria for instituting mechanical ventilation. Patients in different hospital studies may not have started with equal chances of survival.

In addition, methodological differences, such as how "survival" is defined, abound. Studies that measure survival of ventilator patients only in the short term (e.g., survival of the ventilation episode or survival until hospital discharge) probably overestimate the benefits of mechanical ventilation. On the other hand, the benefits of this technology may be underestimated if one attributes all mortality of ventilated patients to the ventilator. A mechanical ventilator cannot be expected to protect a patient from myocardial infarction or any of the numerous other dangerous conditions that threaten all critically ill patients and many healthy elderly individuals. Furthermore, mortality sometimes results from instituting mechanical ventilation *too late* (83).

OTA's review of the literature from 1973 to 1985 found eight clinical studies that examined survival rates among patients receiving mechanical ventilation in acute care hospitals. Despite problems of comparability and some dissimilar results, the available studies reveal a general consistency—i.e., mortality among critically ill ventilator patients is high, and it increases with increasing age. As shown in table 6-6, the five studies that reported survival rates for patients in ICUs, found survival rates ranging from 36 to 89 percent, with an average of 63 percent. In five of the six studies that reported survival of critically ill ventilator patients to hospital discharge, the survival rates were even lower, averaging 55 percent. In the months following hospital discharge, survival rates dropped even further.

Table 6-6.—Survival Rates for Patients Receiving Mechanical Ventilation in Acute Care Hospitals, All Ages

Study	date	Number of patients	Patients' ages	Minimum ventilation	Survival rate: In ICU	Survival rate: To hospital discharge	Survival rate: 1 Year
Nunn, et al.	1970-74	100	0 to 75+	4 hr.	67%	47%	N.A.[a]
Pierson, et al.	1971-72	113	70 to 95	1 hr	N.A.	51%	N.A.
Petheram & Branthwaite	1972-77	91	3 to 75	N.A.	N.A.	54%	38%
Zwillich, et al.	1972-73	314	15 to 95	1 hr.	64%	N.A.	N.A.
Davis, et al.	1975-76	104	Mean 66.7	48 hr.	N.A.	44%	37%
Schmidt, et al.	1976-77	137	N.A.	48 hr.	36%	N.A.	30%
Witek, et al.	1980	100	17 to 70+	N.A.	60%	50%	33%
McLean, et al.	1982-83	1,010	14 to 95	N.A.	89%	82%	N.A.

[a] N.A. = Not available

SOURCES: 1. J.F. Nunn, J.S. Milledge, and J. Singaraya, "Survival of Patients Ventilated in an Intensive Therapy Unit," *British Medical Journal* 1(6177): 1525-1527, June 9, 1979.
2. D.J. Pierson, T.A. Neff, and T.L. Petty, "Ventilatory Management of the Elderly," *Geriatrics* 28(11): 86-95, 1973.
3. I.S. Petheram and M.A. Branthwaite, "Mechanical Ventilation for Pulmonary Disease," *Anaesthesia* 35:467-473, 1980.
4. C.W. Zwillich, D.J. Pierson, C.E. Creagh, et al., "Complications of Assisted Ventilation: A Prospective Study of 354 Consecutive Episodes," *American Journal of Medicine* 57:161-170, 1974.
5. H.D. Davis, III, S.S. Lefrak, D. Miller, et al., "Prolonged Mechanically Assisted Ventilation: An Analysis of Outcome and Charges," *Journal of the American Medical Association* 243(1):43-45, 1980.
6. C.D. Schmidt, C.G. Elliott, D. Carmelli, et al., "Prolonged Mechanical Ventilation for Respiratory Failure: A Cost-Benefit Analysis," *Critical Care Medicine* 11(6):407-411, 1983.
7. T.J. Witek, Jr., E.N. Schachter, N.L. Dean, et al., "Mechanically Assisted Ventilation in a Community Hospital: Immediate Outcome, Hospital Charges, and Follow-up of Patients," *Annals of Internal Medicine* 145:235-239, 1985.
8. R.F. McLean, J.D. McIntosh, G.Y. Kung, et al., "Outcome of Respiratory Intensive Care for the Elderly," *Critical Care Medicine* 13(8):625-629, 1985. © by Williams & Wilkins, 1985.

Published studies from Denver (85,87,88,129); Philadelphia (95); Toronto (75); and London (83) have consistently reported that mortality is highest for ventilator patients who are elderly. While noting that advanced age is an important predictor of survival, however, almost every author is quick to point out that age *alone* is not a good predictor. Other factors that bear on survival include primary disease process (21,81,98,128); number of failed systems (27,59); time to reversal of organ failure (21); and specific physiological values (98).

OTA found only two studies that specifically examined survival among *elderly* patients receiving mechanical ventilation in the hospital. The first study, by Pierson and colleagues (88), followed all 113 patients over age 70 who were treated with mechanical ventilation at either of two Denver hospitals between January 1971 and December 1972. The investigators found that survival to hospital discharge—51 percent overall—declined with increased patient age, but that differences among subgroups of elderly patients (i.e., 70 to 74, 75 to 79, and 80 to 95) were not statistically significant. The researchers concluded:

> These data do not support the contention that mechanical ventilation in the elderly is inappropriate or usually unsuccessful. On the contrary, they suggest that the potential gains from such treatment may be as great in this age group as in any other . . . (88).

The second study of elderly ventilator patients, by McLean and colleagues, was conducted in the respiratory ICU (RICU) of St. Michael's Hospital, an affiliate of the University of Toronto (75). Results of this study are displayed in tables 6-6 and 6-7. The first observation is that survival rates for each age group in this study are high relative to the survival rates in the other studies summarized in table 6-6. (This is explained by the RICU's pol-

Table 6-7.—Survival Rates for Patients Receiving Mechanical Ventilation in the St. Michael's Hospital Respiratory Intensive Care Unit, by Age

Age	Number of admissions[a]	Survival rate: To ICU discharge	Survival rate: To hospital discharge
14-19	4	100%	75%
20-34	50	94	88
35-44	102	93	91
45-54	213	95	92
55-64	377	91	86
65-74	213	80	69
75-95	54	76	54
Total	1,013	89%	82%

[a] Thare were eight repeat admissions and five patients of unknown age among 1,010 patients.

SOURCE: Adapted from R.F. McLean, J.D. McIntosh, G.Y. Kung, et al., "Outcome of Respiratory Intensive Care for the Elderly," *Critical Care Medicine* 13(8):625-629, 1985. © by Williams & Wilkins, 1985.

icy to admit only those patients with cardiorespiratory failure due to "potentially reversible causes"). Equally clear from the figures in table 6-7 is the decline in survival rates with increasing patient age. The researchers attributed this in part to the fact that more of the younger patients were in the RICU following elective cardiovascular surgery (19). Survival rates were significantly lower for patients over age 75 than for younger patients. However, no difference was found in survival rates between subgroups of patients 65 to 74 versus 75 and older. On followup of the St. Michael's patients conducted between 12 and 24 months after hospitalization, 18 of the 49 patients over age 75 were alive, and 14 of them were living in their own homes. The researchers concluded that some elderly patients can benefit from mechanical ventilation and that a patient's age alone does not have good prognostic value.

Chronic Ventilator Dependence

For many patients, especially those with chronic or degenerative diseases (e.g., muscular dystrophy, spinal cord injury or disease), medical stability with chronic ventilator dependence is the best realistic outcome. For others, chronic ventilator dependence is an unexpected, devastating outcome. For individual patients with irreversible disease processes, "failure to wean" is often impossible to predict prior to instituting mechanical ventilation (21). Some observers regard inability to wean as a "feared but rare complication" (34).

Although the risk of failure to wean is probably greatest for patients with conditions associated with advanced age (e.g., COPD), the patient's age is not the critical factor. Experience with 355 ventilator-dependent patients treated between 1980 and 1985 at the Prolonged Respiratory Care Unit of Minneapolis' Bethesda Lutheran Medical Center led investigators there to conclude that "age is not a deterrent to attempting the weaning process" (21). Difficult weaning and failure to wean are associated with a variety of factors that originate either in the patient, the ventilator system, or the artificial airway (50).

Physicians working in pulmonary rehabilitation hospitals have provided OTA the following information about patients at their institutions requiring prolonged ventilatory support. At New York City's Goldwater Memorial Hospital, most of the patients who require long-term mechanical ventilation are elderly persons with chronic lung disease or neuro-muscular-skeletal diseases. Although they must remain in the hospital with mechanical ventilation indefinitely, most of these patients are judged to have "quite favorable" prognoses. Most of them are said to remain mentally competent and to lead satisfying lives within the rehabilitation milieu of the hospital, for from 1 to 10 years (21).

The Prolonged Respiratory Care Unit at Minneapolis' Bethesda Lutheran Hospital is a regional center, serving ventilator-dependent patients from the entire upper Midwest. The majority of patients are over 60 years old, and nearly half of those individuals are over 70. Between August 1979 and April 1983, patients had lengths of stay ranging from 2 to 831 days, with an average stay of 148 days (52). Of the 86 patients admitted during the first 9 months of 1985, 73 percent survived and 71 percent of them were completely weaned (21).

Complications Associated With Positive Pressure Ventilation

The incidence of complications associated with positive pressure mechanical ventilation and intubation, especially in acute care, is high. Complications range from relatively minor conditions, such as elevated body temperature, to severe and potentially fatal complications including obstruction or displacement of the tracheostomy tube, pneumothorax, pulmonary emboli, and nosocomial pulmonary infections.

Above-atmospheric pressure during inspiration, never present in a spontaneously breathing individual, frequently results in decreased arterial blood pressure and decreased cardiac output, potentially causing inadequate blood return to the heart (99).

Controlled mandatory ventilation produces a "clinically important" decrease in renal function (110). In one study of 100 patients ventilated for a minimum of 48 hours, 18 suffered associated renal failure (27). Impaired renal function, in turn, often leads to increased retention of water and salt, which sometimes is associated with, among other things, respiratory problems.

One study reported 400 individual complications or potential complications in 354 episodes of acute mechanical ventilation (129). The above-cited study of patients who required ventilation for 48 hours or longer reported that 11 percent experienced life-threatening complications (27). A 1981 review cited one study in which serious complications were associated with long-term endotracheal intubation in 4 percent of patients and another in which serious complications accompanied 16 percent of tracheostomies (112). For adults, the risk of most complications is not affected by increased age (105), but even minor complications can lead to increased morbidity and mortality in patients who are already critically ill or severely debilitated. When complications are identified promptly, steps to prevent serious consequences can usually be taken (85).

Effects on Mental and Physical Functioning

Improved Mental Functioning

Many patients with even mild chronic respiratory insufficiency have chronically impaired mental function due to hypoxia (i.e., insufficient oxygen) or hypercarbia (i.e., an excess of carbon dioxide). Even in mild degree, these conditions are associated with fatigue, hypersomnolence, and decreased mental function (21). Patients in acute respiratory failure are frequently severely hypoxic and their level of consciousness may, as a result, "be grossly altered" (111). Mechanical ventilation with or without supplemental oxygen (or, for less serious cases, supplemental oxygen alone) can correct the exchange of oxygen and carbon dioxide and thus may improve a patient's mental functioning, alertness, and clarity of thought (21).

Discomfort

Positive pressure ventilation imposes numerous stressful physical effects. These effects, which are at their most extreme for acutely ill patients, have been described not so much as "pain," which can be relieved in most cases by morphine or other drugs, but as a multitude of relatively minor complaints that add up to what one survivor called a condition of being "chronically uncomfortable" or "just plain *miserable*." Contributing to the patient's discomfort are such things as "the raw post-tonsillectomy feeling in one's throat after a nasogastric tube has been in place for 31 straight days," chest tubes reminding you every time you try to breathe or move, nausea, abdominal cramps and hiccoughs (related to swallowing of air and distension of hollow organs), feeling dirty, having a bad taste in your mouth, and fatigue (124). Other causes of discomfort related to the ventilator are: ability to take only shallow breaths, potential hypoxia (resulting in restlessness, confusion, change in blood pressure, or tachycardia), heavy tubing, impaired ability to cough, inability to yawn or sigh, impaired ability to swallow, and overheated air (71).

Patients who are unable to move secretions from the lungs by an effective cough must routinely undergo "one of the most unpleasant experiences that a ventilator patient has"—suctioning (71). The technique for removal of secretions from the airway involves passage of a catheter through the trachea and into each mainstem bronchus, with the application of suction for 10 to 15 seconds.

Eating Difficulties

Ventilator patients who are intubated endotracheally, i.e., through their nose or mouth, can take no food or liquid by mouth. Those who require endotracheal intubation of more than 2 or 3 days (as well as those who are malnourished) require tube feeding or other forms of nutritional support (see ch. 8). Patients intubated by tracheostomy, on the other hand, can eat if they have normal swallowing ability.

Speech/Communication Problems

Inability or severe restriction in speech is a pervasive problem for patients receiving positive pressure ventilation. Those who are intubated endotracheally cannot speak. Tracheotomized patients can speak during ventilator-delivered inspirations if the tracheostomy cuff is partially deflated or if they have special "speaking-cuffed" tracheostomy tubes (45). These options are only feasible, however, for patients who are medically stable with stable respirations (68).

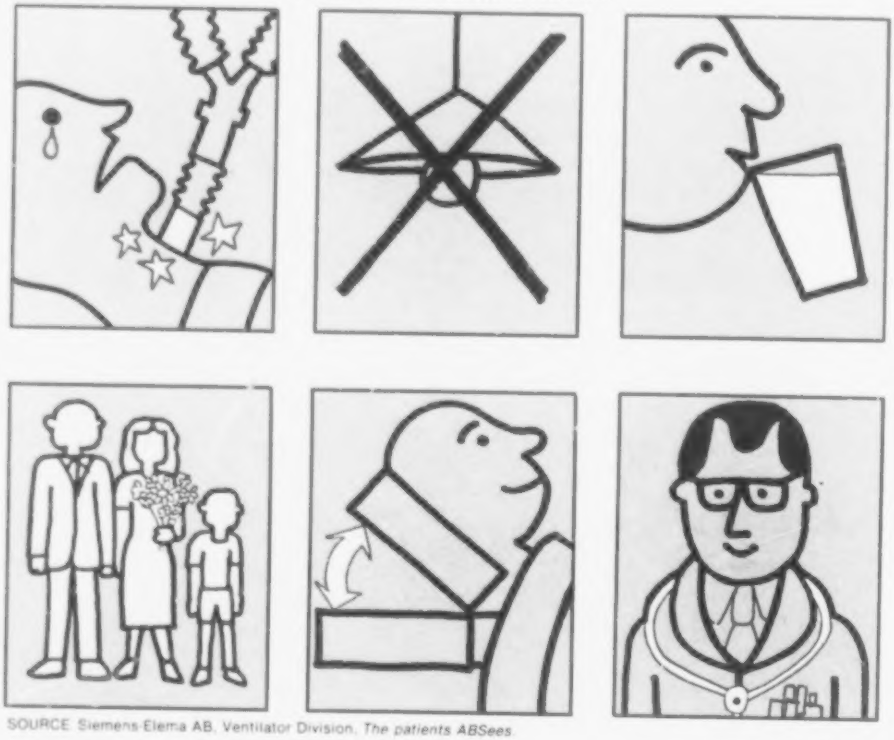
Communication problems can be a major source of frustration for ventilator patients as well as their family members and caregivers. Patients' fears regarding their prognosis and the procedures and equipment to which they are subjected may make the need to communicate especially intense. Patients who are sufficiently alert may try to express themselves in writing. Computers and other much simpler devices (e.g., the "Speak and Spell" toy) may be used. Some patients are helped by provision of a poster or set of cards depicting things patients frequently want to express, such as "I'm thirsty," "I want to go to sleep," "I want my family," etc. (One communication aid of this type, "The Patient's ABSee," developed by Siemens, is shown in figure 6-1.) Other forms of nonverbal communication include hand-squeezing and other kinds of signals that might be established before the patient is intubated. Maximizing the patient's ability to communicate helps restore his or her sense of control and sense of personal value (38). For acutely ill patients, nonverbal communication options are reduced by sedation, medication, confusion, and limited mobility.

In the nursing literature, ventilator patients' difficulty in communicating is regarded as probably the patients' most pressing problem (36). Communication problems may be not merely frustrating, but dangerous. One former ICU patient reported:

> On two occasions, the janitor pulled the respirator plug out of the socket without realizing it, leaving me on a closed system with no movement of air. I am told that emergency alarms were supposed to go off, but my only memory was having to detach the respiratory tube from the tracheostomy myself in order to breathe room air (124).

The inability to call out for help is a source of great fear. Psychologists studying the matter have suggested that the inability to communicate triggers feelings of helplessness and despair that may negatively affect the course of the illness (94). Communication problems are made still worse by the fact that too few caregivers and visitors know how to talk to a person who is critically ill or appreciate how much these patients crave human contact.

Figure 6-1.—Patient's ABSees



SOURCE: Siemens-Elema AB, Ventilator Division, *The patients ABSees*.

> It becomes a matter of routine for the staff to frequently check the ventilator and all the tubings, connections, etc. All too often this is all that is done—that is, we check the equipment but forget about the patient who is lying there worrying if everything is working correctly. A simple statement to the patient such as, "Everything checks out fine," could go a long way to reassure the patient that not only is the equipment functioning, but that the staff is concerned enough to check the ventilator frequently and verify that it is working (36).

Decreased Mobility

Patients tethered to a stationary mechanical ventilator are partially or totally immobilized. Limited mobility brings physical discomfort, as well as the risk of developing embolism, phlebitis, and pressure sores. In addition, the loss of control over one's physical movements is often experienced as a constant fear of falling (out of bed). Perhaps most serious is the physical "deconditioning" associated with remaining relatively still for an extended time and nonuse of the muscles of respiration (71). This is manifested by general weakness and, after about 3 days of continuous ventilation, specific deconditioning of the respiratory muscles that makes weaning from the ventilator more difficult after that time.

For ventilator patients who do not need to be confined to bed, portable ventilators allow mobility and a variety of physical activities. Even with portable ventilators, however, logistical constraints remain. Furthermore, portable ventilators can only be used as the primary device for selected patients.

Psychological Outcomes of Mechanical Ventilation

A patient's experience of severe respiratory impairment and treatment with mechanical ventilation, as with other life-threatening illness and treatment, is a function of a variety of personal and environmental factors. Among the most important are the patient's personality, prognosis, level of consciousness, social support, the quality and sensitivity of care received, and treatment setting. Individual patients cope better or worse with the physical, psychological, and social stresses to which they are subjected.

These topics are addressed to some extent in the nursing literature and in a handful of articles by former or chronic ventilator patients; the scant attention to these topics in the medical literature is conspicuous except for some interest in patients' psychological reactions to ICUs in general. In one study of the psychological effects of ventilation, the dissimilar perspectives of patients and their family members, on the one hand, and nurses and physicians, on the other, was singled out by the researchers as their most striking finding (94).

Initial Reactions to Mechanical Ventilation

Acutely ill ventilator patients experience many of the significant psychological outcomes of mechanical ventilation that are characteristic of critical illness, institutionalization in general, and the ICU environment in particular. Intense physical problems, sleep deprivation, and medication interact to produce psychological problems that may include depression, confusion, disorientation to time and place, anxiety, and acute delirium, along with fears of permanent dependency and preoccupation with death. These effects are particularly disturbing to acutely ill patients who are self-aware. One former ventilator patient described his "psychotic thinking" and loss of emotional control as frightening and embarrassing. He feared that he might recover physically but not mentally, and worried about his ability to resume his career, family roles, etc. (124). Difficulties in communicating, as described above, and the lack of privacy typical in hospitals may exacerbate these problems.

Initially, for many patients experiencing the difficult breathing that is characteristic of respiratory distress, the assistance offered by the ventilator provides a great sense of relief (71). Often, however, this relief is subsequently replaced by a sense of lost autonomy and lost control.

> The patient . . . being mechanically ventilated is expected to trustingly permit others to manipulate his physical and psychological self, his environment, and his significant others. A formerly independent, self-reliant human being must breathe artificially and be fed intravenously; he is dressed and undressed, bathed, pulled, pushed, and moved about without much control over his keepers or himself. Finally, he finds his physical

> and psychological nakedness exposed to strangers who have varying levels of empathy (71).

Psychological discomfort can be minimized by skillful caregivers and visitors. The sources of psychological distress include inadequate information about why the ventilator is needed, its reliability and alarm system, lack of confidence in the caregivers, difficulty communicating, lack of privacy, loss of sleep, sensory deprivation or overstimulation, and loss of power and control.

Conscious adult patients on mechanical ventilation may experience what have been identified as "the problem of threat," "the problem of loss," and "the problem of meaning" (38). According to this analysis, in the early phases of treatment, ventilator-dependent patients exhibit a pervasive anxiety about their survival. Feelings of being threatened are reflected in fear of mechanical failure of the equipment and in a love-hate relationship to it. Many patients display a "hostile gratitude," toward the ventilator and the caregivers on whom they are dependent. According to one formerly ventilator-dependent patient, "It was the enemy. How dare a mass of steel and dials and tubing take control of my life?" (38). In contrast, another ventilator patient described the life-sustaining devices as "friends."

Loss of spontaneous breathing is accompanied by loss of the ability to communicate, eat, and move. Illness and institutionalization bring loss of social roles within the community and family, loss of accustomed life style, loss of positive body image and self-image, loss of privacy, and general loss of independence. For elderly patients, ventilator-related losses come at a time when other serious losses—retirement, income, social status, friends, or spouse—are accumulating. Behavioral responses to this multitude of losses are said to resemble grief behavior, with a period of denial followed by a period of depression. The ventilator patient's greatest psychological problem is the lack of control, the inability to do anything for oneself or for anyone else.

By the same analysis, the other most serious problem ventilator patients face is the need to reassess or reorder their basic values, "to discover meaning in a drastically altered state of existence" (38). This is sometimes described as a religious crisis, focused on the struggle between living and dying, and between meaning and despair.

Ironically, for patients who improve to the point where weaning from the ventilator can be attempted, *independence* from the ventilator can engender tremendous fear and anxiety (36), sometimes severe enough to impede the weaning process (61).

Adjustment to Chronic Ventilator Dependence

Available information about the psychological effects of chronic ventilator dependence pertains to patients who have been able to leave the hospital. These individuals are medically stable, have been through a period of rehabilitation designed to help them adjust to their new lifestyle, and have an established support system. To date, few elderly patients have been included in this exceptional group.

Survivors of the polio epidemics of the 1940s and 1950s constitute a special group of ventilator-dependent patients. Of an estimated 300,000 persons who survived polio with some degree of disability, there were, in 1959, 1,200 who were ventilator dependent (63). Some of these people have remained ventilator dependent ever since and now are approaching age 65.[14] Despite more than 25 years of ventilator dependence, many of these patients have managed to maintain a positive outlook, as the following cases illustrate (62):

> Statement by a 52-year-old respiratory polio quadriplegic, ventilator dependent since age 23: "By being disabled we do miss out on many things. Yet the kindness and consideration that we receive from others compensates in some small measure. . . . After several years at home with my husband and son, I ended up with pneumonia and a blocked lung and moved to Pearson.[15] In the early 1970s I switched to positive pressure via trach full-time. . . . I knit with a mouthstick and enjoy reading and music. . . . I live one day at a time and look forward to tomorrow."

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[14] Also, some polio survivors are experiencing the delayed respiratory problems typical of *post-polio syndrome* and face the possibility that mechanical ventilation will again become necessary (63).

[15] A long-term respiratory rehabilitation facility in Vancouver, British Columbia.

> Statement by a 52-year-old respiratory polio quadriplegic, ventilator dependent since age 30: "I was living with my husband and seven children when I contracted polio. . . . This is certainly not the kind of life I would have chosen, but since it is the one I'm living—I'm going to *live* it."

OTA found no information describing the polio survivors or others whose psychological response to ventilator dependence was poor. However, one article, based on the author's personal experience, suggests that psychological problems among disabled people in general are great and that these problems have been ignored by the mental health professions (37). The author of that article estimates that at least one-third of spinal cord injured persons, many of whom are ventilator dependent, suffer serious anxiety or depression:

> Morbid passivity is common. Drug and alcohol abuse levels are high. Between 12 and 50 percent of all deaths of spinal cord injured persons is by their own hand (37).

A significant aspect of adjustment to chronic ventilator dependence is actually adjustment to institutionalization or to an otherwise changed living environment. Initiation of mechanical ventilation always necessitates a period of institutionalization and is frequently, especially for elderly persons, the precursor to permanent institutionalization. A person who had been living in his or her own home must be transferred to the acute hospital and, subsequently, perhaps to a long-term care facility. For patients already in a nursing home, the need for ventilatory support typically requires transfer to the acute hospital and may preclude return to the nursing home. Even home care may involve a major adjustment—especially if it requires the patient to move in with adult children or vice-versa.

Effects on the Patient's Family and Caregivers

As is any life-threatening, lingering, and costly illness, ventilator dependence is stressful not only for the patient, but for those around the patient. For the spouse and children, serious illness and hospitalization can be physically, emotionally, and financially exhausting. In addition to the strain of frequent trips to and from the hospital over an extended period, the severity of the patient's condition puts the family "through many emotional highs and lows" (77).

In the early days or weeks of mechanical ventilation, family members typically experience the same kinds of grief reactions that alert patients experience. Like patients, they need understanding and communicative professionals to help them cope with the changed situation of their relative, its impact on their own lifestyle and, perhaps, its spiritual meaning (38). The strain may be particularly great on the adult children of elderly ventilator patients. This "generation in the middle," often must, simultaneously, meet responsibilities to their (possibly several) elderly parents and their own children, as well as their spouse, work, etc. (15).

The effects on the family are perhaps greatest when a patient returns home and family members participate in their care. Certainly, home care offers a far greater sense of normalcy and the opportunity for the family to stay close. However, having the patient at home means the patient's family "will be solely responsible for a patient's life." According to one observer, the "very mention" of this fact "is overwhelming for the long-term ventilator-dependent patient and his family" (77) whose members must be responsible for routine patient care and equipment maintenance, recognizing signs of distress in the patient, and knowing how to handle emergencies. Caring for a ventilator-dependent person is a difficult, responsible, round-the-clock job. Its time demands alone, if not the economic and emotional drain, can drastically change a family's lifestyle; in a sense, the whole household becomes tied to the machine.

Often, the physical and psychological load on family caregivers is lightened if more people share the work. Also, if financial resources permit, the family's workload can be lightened by employment of nurses, attendants, and other helpers. For elderly patients, both the number of relatives who are available to help and the feasibility of purchasing assistance may be reduced.

Caring for critically, terminally, or chronically ill ventilator patients also takes a toll on physicians, nurses, and other professional caregivers. Unlike patients and family members, professional caregivers, especially physicians and special respiratory personnel, are involved with illness and ventilator-dependent patients by choice. Still, caregivers who are constantly faced with dying patients, grieving families, and their own fallibility are under enormous stress, which can lead to personal problems, "burnout" and possible effects on the quality of care they can provide (see ch. 10).

MAKING DECISIONS ABOUT STARTING AND STOPPING MECHANICAL VENTILATION

Decisions about the use of mechanical ventilation for individual patients are highly specific and individualized, ideally focused on a comprehensive assessment of one patient's condition and prognosis and taking into account his or her personality and personal wishes. Such decisions occur within the context of the laws, ethics, and customs of the society, as well as the specific governmental, institutional, and professional policies that limit what is possible and what is permissible. Such decisions are also influenced by the diverse perspectives and objectives of the numerous parties involved in the decisionmaking process.

Some of the decisionmaking dilemmas that arise in the care of individual patients are illustrated by the following case:

> **A 58-year-old woman had suffered progressive muscle weakness finally diagnosed as amyotrophic lateral sclerosis . . . Marked bulbar weakness was present and swallowing became difficult resulting in a 20-pound weight loss . . . she presented in a very cachectic state. The attending neurologist decided that a feeding gastrostomy was needed to avoid further starvation. . . . The gastrostomy was placed . . . but in the immediate postoperative period the patient was very weak and required a mechanical ventilator. The next morning she was awake and alert and an attempt at extubation was made. Within 3 hours, the patient was diaphoretic and suffering anxiety and air hunger. She was therefore reintubated and rested quietly with ventilatory assistance. The use of the feeding gastrostomy tube was begun, but strength did not return. Discussions between the consulting respiratory care team and neurologists then began for the first time. Also the family sought discussions with the consulting respiratory care team. The possibility of a continuing "life" with ventilatory support had never occurred to either patient or family. Both the patient's daughter . . . and the patient herself became angry over the "entrapment," yet neither could face the realities of death. At this writing, the patient remains in a totally paralyzed state and on a mechanical ventilator (84).**

The most fundamental decisions that must be made about mechanical ventilation are: 1) whether to initiate or withhold it, and 2) whether to continue or withdraw it. These decisions frequently are not end-points, but rather part of a *continuum of momentous decisions*. That is, decisions about mechanical ventilation are often preceded by decisions about diagnostic tests, admitting the patient to the hospital or to the ICU, and providing resuscitation. And, the decision to initiate mechanical ventilation is often followed by decisions concerning the transfer of a patient from one setting to another and the provision of other life-sustaining technologies in the event of complications or new illness. In making a decision about the use of mechanical ventilation for a particular patient, caregivers, patients, and family members must be prepared to make subsequent difficult choices, and policies must be broad enough to leave open all suitable options.

Complicating decisions about initiation of mechanical ventilation is the fact that the need for ventilation is sometimes unforeseen. In some situations, the diagnosis is known and the patient's eventual need for mechanical ventilation can be anticipated. For patients with progressive diseases like COPD and ALS, for example, eventual respiratory failure may be foreseen over a period of years. There is time for collection of data pertinent to the prognosis as well as the patient's wishes. In other situations, however, patients experience respiratory failure without warning. When a patient is in the throes of acute respiratory failure, there is no time to make a careful diagnosis, to determine his or her wishes, or to inform the patient and gain consent for intubation and initiation of ventilation.

Patients in respiratory failure are typically unconscious or, at best, in a severely altered mental state due to hypercapnia, acidosis, and/or hypoxia. Even once ventilated, some patients remain in a compromised mental and emotional state that impairs or precludes their ability to participate in decisions about their treatment. For decisions about mechanical ventilation in these patients, caregivers and family members acting as surrogates frequently play a fundamental role (see ch. 3 and OTA background paper on surrogate decisionmaking by A. Buchanan, M. Gilfix, and D.W. Brock (16).

Decisions about the use of mechanical ventilation are also very difficult for the health professionals who are regularly involved in them. A recent workshop on "Withholding and Withdrawing Mechanical Ventilatory Support," sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and several professional organizations,[16] provided valuable insights into the process of and problems in clinical decisionmaking (see app. E). Physicians expressed humility with respect to the difficult clinical decisions they must frequently make and particular trouble with the conflicts in their joint roles as patient advocate and hospital employee. This workshop was regarded by the invited experts as a historic event, signifying important change in clinicians' attitudes about mechanical ventilation and, in particular, their widely held belief that the technology has come to be used too frequently in cases where the patient does not benefit. Perhaps, suggested one physician, if more attention had been paid 10 years ago to decisionmaking about *initiating* mechanical ventilation, a workshop on withholding and withdrawing would not have been needed (107).

Physicians have different views about their role in the decisionmaking process. Some physicians believe that decisions about ventilatory support are entirely medical. The patient or surrogate must give permission for the physician's decision to be carried out; but patients should not be expected, perhaps not even allowed, to "shoulder the burden" of such a grave decision (58). Others find this view paternalistic and believe the physician's role should be mainly to educate and advise patients regarding treatment options. Ultimately, the attending physician is responsible for the patient's care and is legally liable for action taken or not; thus, the attending physician usually makes the final decision or reviews the decision of house staff. Increasingly, physicians view themselves as members of a decisionmaking team, whose role is to facilitate consensus of the, possibly disparate, perspectives represented by the patient, family members, consulting physicians, and other health professionals (see ch. 10).

Clinical Considerations

Clinical evaluation of a patient's condition is the logical first component of the decision process. Details of a patient's physiological condition are needed both for decisions about whether to initiate mechanical ventilation and about *when* to initiate it. Respiratory insufficiency or failure is not always apparent by clinical observation alone, particularly in elderly patients.

> The clinical manifestations of acute respiratory failure . . . are nonspecific and seldom point directly to the lung; in the elderly they may be especially subtle. The most frequent signs—restlessness, confusion, and tachycardia—may be interpreted in the elderly patient as "sundowning," "senility," or just "cantankerousness," and may not arouse concern until respiratory arrest or other serious complication occurs (87).

The clinical evaluation includes objective measurement and analysis of air volumes and pressures, blood gases, electrocardiogram, and changes in heart rate. Other important clinical observations include vital capacity, breathing rate, inspiratory capacity, tidal volume, and the degree of physical and mental exhaustion. Because of time limitations and variations in facilities, complete data may not be available.

For each of the measurable parameters, levels indicating adequate ventilation have been determined; for some parameters, however, there is a range of acceptable values. The patient's precipitating conditions and previous state must be taken into account: "absolute blood gas levels" are "difficult to assign" (111). In patients with established chronic respiratory insufficiency, interpretation of blood gases is particularly difficult (111). Thus, moving from physiological assessment to treatment decisions may still be very difficult. "Laboratory and clinical findings," according to the American Association of Critical-Care Nurses Procedure Manual, "*aid* [emphasis added] the decisionmaking process" (74).

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[16] Cosponsors were the American Association of Critical-Care Nurses, American Association for Respiratory Care, American College of Chest Physicians, American Thoracic Society, and the Puritan Bennett Foundation. The workshop was held in Washington, DC, Sept. 30 through Oct. 2, 1985.

Other clinical considerations focus on the patient's prognosis and judgments about whether or not mechanical ventilation will improve it. Prognostic uncertainty is the nemesis of clinical decisionmaking. Will the patient live or die? Will weaning be possible or will the patient be permanently ventilator dependent? What will be the quality of the life saved? For elderly patients, as any others, clinicians must be able to incorporate their knowledge and experience of previous patients into decisions without making unjustified generalizations about likely outcomes. Clinicians at the NHLBI workshop rejected chronological age as an independent predictor of the outcomes of mechanical ventilation and expressed great interest in prognostic tools currently being developed. The need for better means of predicting the outcome of mechanical ventilation is clearly reflected in the following comment:

> We should accept that we really are only slightly wiser than the apes in regard to the science of living and dying and that we know very little about quality of life or the balance between a life of terror or a death of peace. When making an irrevocable decision for someone else, our actions should be guided by a notion of our fallibility and a surge of humility. . . . I have witnessed many instances where nature, in its greater wisdom, has taken the final step out of my hands and made my puny efforts at life-support impotent. In other words, when the end has come, it has come, and often there is not much for us to decide. The opposite may occur when, with great solemnity, we switch off the respirator, and the patient goes on living and may perhaps do even better than he had previously. . . . (11).

In deciding whether it is appropriate to continue or discontinue ventilation, caregivers consider many of the same physiological parameters that were used to determine the need to initiate ventilation. Clinical evaluation of the appropriateness of continuing ventilation includes determination of the patient's basic condition, acute or chronic disease; whether the patient's need is for a breathing aid, for oxygen, or for airway patency;[17] and the likelihood of the patient's ability to sustain spontaneous breathing.

Decisions to stop mechanical ventilation may take one of two dramatically different forms. On the one hand, there may be a decision to wean the patient from the equipment he or she has become dependent on, with the goal of restoring normal spontaneous breathing. Ventilator patients who are stabilized and able to breathe spontaneously for 10 minutes out of an hour are widely regarded as ready for weaning. The clinical evaluation of a patient's readiness for weaning also includes assessment of possible psychological dependency. For patients who are terminally ill, complete weaning from the ventilator is usually not feasible, but the possibility of temporary or partial weaning should still be considered. Since restoration of ventilator independence is the best possible outcome for the patient and, since it represents therapeutic success for caregivers, the decision to attempt weaning is relatively unproblematic.

In almost every case where the patient is ventilator dependent, the need eventually arises to determine whether continued ventilation is indicated or whether further treatment is futile. If the patient is terminally ill, and especially if the patient is in a permanent noncognitive state or brain dead, clinicians might recommend that ventilation be discontinued or withdrawn. In contrast to weaning, a decision to discontinue or withdraw mechanical ventilation signifies the removal of equipment without which the patient is not expected to survive. In such cases, some physicians advocate what they call "terminal weaning," i.e., the deliberate, gradual withdrawal of ventilation from a patient for whom further treatment is deemed to be futile. Whereas simply "pulling the plug" can cause abrupt and painful dying, withdrawal of the ventilator over a period of hours usually permits the inevitable death to proceed peacefully (46).

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[17] Patients who have been successfully weaned from a ventilator may be unable to maintain a patent airway. Therefore, removal of the artificial airway may have to be delayed. Readiness for extubation is indicated by a vigorous cough capable of clearing secretions from the airway. Also, many patients who no longer require mechanical ventilation cannot be weaned from supplemental oxygen.

Many of the physicians, nurses, and respiratory therapists at the NHLBI workshop expressed strong opinions that despite lawyers' and ethicists' claims to the contrary, (90) at-the-bedside decisions to withdraw mechanical ventilation are entirely different from decisions to withhold it. For professional caregivers, the decision to withdraw a ventilator is an admission of failure or an admission that the initial decision to ventilate was wrong (80). Moreover, while patients sometimes participate in decisions to withhold treatment, the decision to withdraw a ventilator is almost always made by people other than the patient. All parties, i.e., family members, and the numerous caregivers who have become involved with the patient, must be prepared for this event. Workshop participants indicated that withdrawal of ventilators occurs much more frequently now than it did 5 years ago (some of this increase results from more frequent initiation) and that families are now more involved in the decision to stop treatment.

Ethical Considerations

The prolonged use of mechanical ventilation with patients of any age raises important ethical issues. These issues have to do primarily with how decisions should be made to initiate, withdraw, or withhold mechanical ventilation for a specific patient, with the balance of benefits and burdens this treatment brings, and with the distribution of technological resources. In the words of one leading pulmonologist:

> . . . all who are seriously involved in respiratory care or intensive care in general recognize that a great deal of harm and suffering can be caused by the inappropriate or irresponsible use of mechanical ventilators in hopeless situations (84).

Some of the ethical quandaries involved in defining what constitutes "harm," "suffering," or a "hopeless" situation, and what is "appropriate" and "responsible" use of this technology are illustrated by the case of the 79-year-old widow outlined here (and detailed in ch. 4).

After short-term treatment with mechanical ventilation for her congestive heart failure and COPD, the patient said she "absolutely refused" to be intubated ever again. Upon subsequent readmission to the hospital, she initially repeated this wish, but said she would accept basic CPR if she suffered cardiac arrest. Over a hospital stay of approximately 40 days, her condition worsened; her lucidity, and her conviction about what treatment she wanted wavered. When she was eventually reintubated, she made it clear that she wanted mechanical ventilation and maximal care. However, in a few days she had lapsed into a coma, and her physicians judged that her condition was irreversible. With the concurrence of her son, a DNR order was written, and she was allowed to die (65).

The ethical principles that are features of the decisions taken in this case are: respect for the patient as a person, yielding to the patient's autonomous wishes, being of benefit to the patient, and avoiding harm through the extension of suffering. This case also illustrates some of the moral and practical difficulties in respecting patients' wishes. By her wish to receive basic CPR but not to be intubated, the patient put her caregivers in a position that some people find illogical, i.e., to restore her circulation but not support her breathing. This indicates some of the difficulties in drawing lines between treatments that are part of a logical continuum, for example, between a full resuscitation code and a limited code (see ch. 5), or between mechanical ventilation and other life-sustaining treatments (23). The significant changes in this patient's medical condition, in her wishes regarding treatment, and in her ability to express those wishes illustrate how, even if physicians are determined to carry out the patient's wishes, it is not always possible for them to do so.

A case in which the patient's family demanded maximum care provides an interesting contrast.

A 75-year-old married man was admitted to the intensive care unit of a university hospital in acute respiratory distress. He was anxious but fully alert and gasping for help. A retired laborer, Mr. Watkins had been suffering from a chronic pulmonary disease for the past 15 years. For the past 5 years he had become progressively debilitated.

Prior to admission he had been confined to his home and depended on his wife for the most basic of care . . . He had been a fiercely independent man and still enjoyed ordering people around. His wife and married son were totally devoted to him.

The diagnosis was bilateral pneumonia, and Mr. Watkins was given antibiotics and put on a mechanical respirator with supplemental oxygen. Within 2 weeks the pneumonia was largely cleared and Sarah Radburn, his physician, began attempts to wean him from the respirator. Unfortunately, he had become "respirator-dependent" as a result of a combination of poor nutrition, possible new damage to his lungs, weakened respiratory muscles, and fear of breathing on his own. Despite a slow, cautious approach with much reassurance, the weaning attempts repeatedly failed. Mr. Watkins, short of breath and terrified, would demand to be placed back on the respirator.

Dr. Radburn rated the ultimate chance for successful weaning as "maybe 20 percent." The patient became more and more discouraged with his lack of progress and the frequent painful medical procedures . . . After 3 weeks of unsuccessful efforts, Mr. Watkins refused to cooperate with further attempts at weaning. His wife and son became concerned that he had given up the "will to live." They begged the medical staff to "do something to save him." Although he had become less communicative, he remained alert and aware and, in the opinion of the staff, was fully competent. He told Dr. Radburn he wanted the respirator disconnected. "I want to die" he said (49).

The possibility of permanent ventilator dependence and the patient's view of this must be included in any comparisons of harms versus benefits in the decision to initiate ventilation in the first place. In the view of Mr. Watkins, dependence on a ventilator 24 hours per day had an overwhelming impact on his quality of life. He concluded that his quality of life on the ventilator was so unsatisfactory that death would be preferable. (The constancy of treatment also seems to put mechanical ventilation in a class by itself from the standpoint of caregivers and other observers. "Physicians seem to find it easier," for example, "to decide not to continue hemodialysis" (47).)

Mr. Watkin's expressed wish "to die" could be interpreted either as suicidal or the more neutral wish to avoid mechanical ventilation. The former interpretation raises additional ethical questions which are of both philosophical and practical concern. Does, for example, the use of a life-sustaining technology sometimes actually facilitate suicide? If caregivers accede to a patient's wish to withdraw treatment, are they assisting suicide? (see ch. 4). Some observers have noted that before caregivers accede to a patient's request to disconnect a ventilator, they must determine whether this request results from conditions that are reversible, such as temporary depression, fear based on misperceptions or misinformation, or underlying problems between the family and patient.

The above case also highlights questions about the role of family members and the proper weight of their wishes. When, as in this case, the patient is alert and able to participate in treatment decisions, there is wide agreement that the family's wishes should always be secondary to the patient's. The family, after all, is not the physician's patient; nor in a case like this is a family member the patient's proxy (96).

> The physician must remember that he has only one client—the patient. He is the advocate of the patient—not the family, nor the welfare agency, nor the kindly clergyman, squeamish at the sight of tracheostomy (32).

Finally, there is an important ethical issue related to when obligations to patients *end*. The initiation of mechanical ventilation for acute care often creates many long-term needs (e.g., for continuing professional services, reimbursement, social support). Indeed, mechanical ventilation itself (and not merely the disease or condition originally leading to its use) may be the cause of a person's loss of spontaneous breathing. Prolonged use of mechanical ventilation can irreversibly suppress spontaneous breathing in some cases in which it might have resumed. Patients and professionals closely involved with this technology suggest there is a need to reconsider how the boundaries of this treatment have been defined (21). Do obligations to a patient end with discharge from an ICU or hospital, or do obligations stand as long as the patient is ventilator dependent? If the latter, reimbursement policies and inadequate community resources that commit some medically stable ventilator-dependent patients to ICUs and some to poverty are in clear need of revision.

Legal Considerations

Mechanical ventilation, as an arbiter of life and death, raises legal questions concerning suicide, assisted suicide, homicide, and medical malpractice. Decisions regarding the use of this technology are greatly influenced not only by laws and court actions (see ch. 3 and OTA background paper on court decisions and legislative approaches, by G.J. Annas and L.H. Glantz (6)) but also by patients' and caregivers' perceptions and misperceptions of these (see OTA background paper on legal perceptions and medical decisionmaking, by M.B. Kapp and B. Lo (56)). Of the life-sustaining technologies that OTA studied, mechanical ventilation was the first to draw legal attention. Some of the recent court cases involving this technology are summarized in box 6-B.

Box 6-B.—Some Recent Legal Cases Involving Mechanical Ventilation

Barber* v. *Superior Court of Los Angeles County (10)

In this case, decided October 12, 1983, a nursing supervisor brought criminal charges against two physicians for acceding to the request of a patient's relatives to discontinue life-support equipment and intravenous tubes. The court ruled that a competent adult patient has the legal right to refuse medical treatment; a physician has no duty to continue use of life-sustaining machinery after it has become futile in the opinion of qualified medical personnel; and there is no legal requirement of prior judicial approval before any decision to withdraw life support for terminally ill patients can be made. Charges against the physicians were dismissed.

Satz* v. *Perlmutter (97)

Mr. Perlmutter was a 73-year-old man with a terminal illness, amyotrophic lateral sclerosis. After trying by himself, unsuccessfully, to remove the ventilator which was keeping him alive, Mr. Perlmutter petitioned the court to allow him to direct his own treatment and to have the ventilator removed. He was mentally competent, and his family approved his decision. The Florida court ruled: 1) he could decide to remove the ventilator; 2) the medical profession should not substitute its judgment for the patient's; and 3) the hospital would not be liable for the result of his decision.

Eichner* v. *Dillon (31)

Brother Fox, an 83-year-old member of the Catholic Order of the Society of Mary had a heart attack during routine surgery. He fell into a coma with severe brain damage and was placed on a ventilator. Two neurosurgeons who examined him agreed that there was no reasonable possibility that he would regain consciousness. A long-time friend, Father Philip Eichner asked the hospital to disconnect the ventilator, but the hospital refused. In court, Father Eichner said Brother Fox had expressed his wish that "extraordinary" life support not be applied on his behalf. The court ruled that there was no reasonable possibility that Brother Fox would ever return to a "cognitive and sapient state," and that when he was competent, he had made clear he would not want this treatment. With the court's approval, mechanical ventilation was discontinued.

Estate of Leach* v. *Shapiro (33)

Following a cardiopulmonary arrest, the 70-year-old woman was successfully resuscitated, but she did not regain consciousness. She remained in a chronic vegetative state, on a mechanical ventilator for more than 5 months until a court order led to withdrawal of the ventilator. Her husband, who was her guardian, had petitioned the court after 2 months to terminate treatment, but his petition was denied. The family alleged that Mrs. Leach had been put on the ventilator and other life-support without her own or her family's consent, although she had expressly advised that she did not want to be kept alive by such machines. The trial court dismissed the case, but the Ohio Court of Appeals subsequently overruled the dismissal (4).

Informed Consent

A patient's legal right to make decisions about his or her health care is well established. Under the doctrine of informed consent, patients have the right to accept or to refuse treatment, as well as the right to request that treatment be withdrawn. Moreover, there are available legal provisions to specify treatment preferences in advance (see ch. 3). Highly publicized court cases have consistently upheld the right of decisionally capable patients to have mechanical ventilation withdrawn.

However, in practice, patient's choices regarding mechanical ventilation are not always known, knowable, or carried out. Exercising the right to direct one's own care requires a patient who is mentally competent, alert, and informed. In the case of respiratory insufficiency or failure, these conditions frequently do not obtain. Disease, medications, pain, and the urgency of the situation may render the patient incapable of participating in treatment decisions.

Informed consent for instituting mechanical ventilation is, at best, difficult to obtain. Participants at the NHLBI workshop emphasized the importance of ascertaining the patient's preferences early and documenting them in the medical record. (They also emphasized the difficulty for both physicians and patients in discussing these sensitive subjects.) Even if time, the patient's condition, and the relationship between the patient and physician permit careful discussion, it may be impossible to fully inform a patient about mechanical ventilation. In fact, some physicians believe that *no one can recognize the impact of being on a ventilator in advance* (67). In a life-threatening emergency, consent is often "implied." When consent is explicitly obtained, it is most often verbal. Often, a patient's silence is interpreted as consent.

If the patient is not decisionally capable, a surrogate decisionmaker or legal guardian, or a court order regarding treatment may be sought. (These mechanisms are reviewed in ch. 3 and analyzed in detail in a background paper to this report (16)). Other legal problems arise from the variation State to State, institution to institution, and physician to physician in how directives by patients or their surrogates are handled.

Because some caregivers are willing to override the patient's wish and because practice and theory are not the same, one respiratory therapist reported:

> Elderly patients are often not active participants and . . . their preference is not an issue in the decision. Many patients are (or are perceived to be) unable to understand, poor communicators or historians, not "responsible" or capable of making decisions, and difficult to deal with. There is usually more involvement by the patient when the care is more long-term. . . . The goals of long-term ventilator management could never be accomplished in a patient who is not desirous of this form of therapy (21).

Advance Directives

By means of a formal advance directive—a living will or durable power of attorney for health care—or informal means, a patient attempts to ensure his or her participation in decisions regarding life-sustaining treatment in general or mechanical ventilation in particular. In some instances, advance directives specify *particular treatments* an individual does or does not wish ever to receive. A patient may, for example, indicate that he or she does want to receive nutritional support, but not mechanical ventilation.

In practice, caregivers do not always comply with a patient's advance directive to withhold life-sustaining treatment. Often there is simply no mechanism or time for discovering that a directive exists or to produce it. In an emergency, or with a decisionally incapable patient, even if the patient has an advance directive, it is unlikely the physician on the scene will know of it. Another reason caregivers sometimes do not comply with a patient's advance directive is that they feel that the directive is not sufficiently clear or that it does not serve the patient's best interest. Some people are skeptical about patients' ability in general to specify treatment preferences in advance. And, some are particularly skeptical about directives made prior to the—terrifying—experience of severe breathing difficulty. According to one physician, "patients who think they don't want to be ventilated change their mind when they are choking to death" (22).

Fear of the Law

The fear of legal liability remains a major issue for caregivers—especially when a patient is not decisionally capable, when the patient's wishes are not known, and when there is disagreement among the patient and family, caregivers, or between caregivers and their employing institution about what to do. Differences in State laws and precedents add to the confusion.

The fear of being sued for malpractice may at once encourage physicians to use all available life-sustaining technologies and discourage them from taking any action that is contrary to the patient's wishes. In practice, these two objectives may conflict, thus adding to caregivers' uncertainty about legally correct action. There has been no successful suit against any physician who followed the wishes of the patient, but there has been at least one case (*Barber* v. *Superior Court of Los Angeles* (10)) in which physicians were accused of criminal intent and murder despite carrying out the family's wishes. Physicians and other health professionals are acutely aware of the possibility of malpractice claims and fearful of what appear to be uncertain and shifting legal boundaries (56). (Malpractice and other legal questions are more fully discussed in ch. 3.)

Professional and Institutional Guidelines

Standards and guidelines developed and promulgated by professional associations and institutions are other important factors in decisions about the use of life-sustaining technologies in general and mechanical ventilation in particular. They help to guide treatment decisions as well as procedures for making those decisions. Although these do not have the force of law, and their intent is usually to solve clinical and ethical dilemmas more than legal ones, they may be used in legal proceedings to determine whether or not acceptable care was provided. They may address a variety of issues, including who should make the treatment decision, where or by whom care should be provided, and when it should not be.

Standards of care (or standards of practice), as established formally or informally by professional associations provide some, limited, guidance in decisions about mechanical ventilation. Although voluntary professional standards serve primarily to assure quality of care (and to protect professional interests), over time, they become the expected norm. In legal proceedings, particularly malpractice cases, health professionals and institutions may be held accountable to the standards of care in their community. Knowing this, health professionals have a keen interest in observing these voluntary guidelines.

One example of professional standards relevant to mechanical ventilation is the "Guidelines for Management in the Home and at Alternate Community Sites," published in 1986 by the American College of Chest Physicians (82). These guidelines identify factors that should be considered in the selection of ventilator-dependent patients for care at home or in other community settings. Another example is the standards of care for providing mechanical ventilation in nursing homes, developed jointly by the American Association for Respiratory Care and the American Health Care Association (1). Among other things, these standards address staffing, quality assurance, infection control, safety, and continuing education.

Such policies and standards may assist in legal proceedings or they may, at times, be the focus of the legal debate. For example, the point of contention in the 1986 case of *Tune* v. *Walter Reed Army Medical Hospital* was a policy of the Department of the Army precluding the withdrawal from any patient in an Army medical facility of life-support systems that have been put in place.

Many institutions now have policies that specify categories of patients who should not be resuscitated. DNR policies (see ch. 5), although usually meant to address only the question of resuscitation, may directly or indirectly resolve or preclude questions about the use of mechanical ventilation. The DNR policy of the Veterans Administration (VA), for example, explicitly states, "a DNR order is compatible with maximal therapeutic efforts short of resuscitation" (122). Patients for whom a DNR order has been written might still receive nutritional support, antibiotics, or mechanical ventilation that had been started; subsequently, however, withholding of resuscitation almost always precludes initiation of mechanical ventilation. In addition, some institutions have "disaggregated

DNR policies," i.e., policies that distinguish Do Not Resuscitate from "Do Not Intubate" (DNI) (e.g., (76)). Patients coded DNI might be resuscitated but not receive mechanical ventilation. Disaggregation of the DNR order is thought by some observers to reduce uncertainty or the possibility that the directive will seem unclear. However, others argue that specifying what treatments should or should not be provided raises new questions about potential treatments that remain unspecified.

In addition to addressing substantive issues, standards of care and institutional policies may address decisionmaking procedures—e.g., documentation in patients' charts, the role of surrogates, ethics committees, etc. In 1976, for example, the Joint Commission for the Accreditation of Hospitals published standards for hospital respiratory therapy departments. These standards require that a physician's order for services indicate the criteria for continuing or ending each therapeutic procedure prescribed. Another example is the VA's requirement of written consent for a tracheostomy (123).

The level of activity surrounding the development of standards and guidelines suggests an awareness within the professions associated with mechanical ventilation that guidance is needed to improve treatment decisions and decisionmaking procedures. It also suggests that professionals are interested in developing these guidelines themselves.

FINDINGS AND IMPLICATIONS

A large proportion of patients who become candidates for mechanical ventilation—and a large proportion of patients whose need for ventilation becomes prolonged—are elderly. Some elderly individuals, although permanently ventilator dependent, manage an active life and maintain a strong will to live. Senator Jacob Javits was an example. Other individuals are severely debilitated and severely brain damaged with no prospect of recovery or rehabilitation. Clinical studies consistently show that mortality, which is high for mechanically ventilated patients in general, is highest for elderly patients. Advanced age *alone*, however, is an inadequate predictor of the outcomes of mechanical ventilation.

Survival, functional capacity, and an individual's ability to cope with prolonged ventilator dependence are often difficult to predict at the time the decision to initiate mechanical ventilation is made. Many physicians and other health professionals involved in mechanical ventilation believe that this technology is frequently used when it should not be. The lack of definitive prognostic measures for patients with respiratory failure subjects some patients to needless suffering and precludes efficient use of health care resources. Research is needed to reduce prognostic uncertainties and to support improved decisionmaking. There has been practically no research focused on the clinical and behavioral aspects of mechanical ventilation with elderly patients.

In patients with chronic or progressive diseases affecting respiration, eventual respiratory failure can be anticipated. When a patient is in acute respiratory failure or unconscious, he or she cannot give informed consent to mechanical ventilation. This observation suggests the special importance of early and frank conversations between physicians and patients and between family members and patients regarding the potential need for mechanical ventilation, and the importance of advance directives that are clear and well-documented.

The decision to initiate mechanical ventilation is frequently only one of several very difficult decisions regarding this technology. As the patient's condition and circumstances change, choices must be made about other medical treatments, and the benefits of continuing ventilation must be reevaluated.

Despite ethical and legal pronouncements to the contrary, caregivers involved in providing mechanical ventilation argue that, at the patient's bedside, the difference between withholding and withdrawing this life-sustaining treatment is vast. Needless suffering and expense could be reduced if there were provisions to make withdrawal of ventilation less difficult when the treatment has proved to be futile or no longer wanted by the patient.

Mechanical ventilation is an extraordinarily expensive treatment, with a large share of the cost borne by Medicare and Medicaid. For hospitals, the cost of treating patients who require this technology sometimes far exceeds Medicare's current DRG-based payments. Thus, hospitals have financial incentives not to treat some seriously ill Medicare patients. In most States, however, limited Medicaid payments for ventilator-dependent patients favor the use of acute care hospitals over other treatment settings.

Interest in providing ventilator care for patients in their own homes and in skilled nursing facilities is strong. To date, however, few elderly ventilator patients have been discharged home, and few nursing homes are able to admit ventilator patients. Some observers warn that extension of Medicare and Medicaid coverage for home care of ventilator-dependent patients would stimulate an explosion of utilization and cost. Those who dismiss this warning argue that no change in reimbursement will change the medical indications for long-term ventilation, and that more liberal reimbursement for home ventilation would permit more efficient use of resources.

There is significant potential for *prevention* of the need for mechanical ventilation. The Surgeon General reports that COPD, the single greatest cause of respiratory failure, would almost disappear if Americans quit smoking. Moreover, the benefits of stopping smoking are significant, regardless of the individual's age and years of smoking.

Ventilator-dependent persons have ongoing needs for resources and services. These needs may be unforeseen or unavailable. In addition to medical care and equipment-related resources, many patients and families need facilities and services to help them cope with the social, emotional, and financial costs of ventilator dependence.

While the burden as well as the promise of mechanical ventilation for individual patients, family members, and caregivers are identifiable, it remains very difficult to assess the magnitude or urgency of societal problems associated with this technology. Data on utilization and cost are very inadequate, and there is no consensus on what constitutes appropriate usage or public expenditure.

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Dialysis for Chronic Renal Failure

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Chapter 7

Dialysis for Chronic Renal Failure[1]

INTRODUCTION

Individuals with end-stage renal disease (ESRD) would die within a few weeks or months if not sustained by some form of dialysis therapy or a kidney transplant. Nearly 91,000 Americans currently receive some form of dialysis (43). As recently as the 1960s, the scarcity and high cost of resources made treatment of chronic renal failure largely unavailable and inaccessible. Treatment was limited to the affluent and the handpicked. So-called "God committees" composed of health professionals and community leaders selected patients on the basis of criteria that included age, race, sex, family responsibilities, employment and financial status, and "social worth." Patients younger than 15 or older than 45 were routinely disqualified for treatment.

The Federal Government's commitment in 1972 to cover the catastrophic cost of treatment for ESRD through Medicare was a pivotal event that has remained a touchstone in subsequent debates about providing expensive medical care for specific groups of patients. Medicare's ESRD program, enacted into law (Public Law 92-603, Sec. 2991) in 1972 and initiated in 1973, is the only Federal program that provides almost complete coverage for a catastrophic illness (5). It is at once a forceful reminder of the problems that may exist *without* Federal intervention and of the problems that may arise *as a result* of intervention.

Largely as a result of the ESRD program, dialysis and renal transplantation are now available to virtually all Americans in need, without regard to age, social status, or ability to pay. Following the program's implementation, there occurred rapid expansion of treatment facilities and personnel and significant advances in dialysis and transplantation technologies (25). Not surprisingly, the number of patients being treated for ESRD increased dramatically. Today, the old problem of access to ESRD treatment has been replaced by one of tremendous public cost. The current cost of providing benefits to ESRD Medicare beneficiaries is about $2.1 billion per year and growing (41).

People over age 65 are now the fastest growing segment of the dialysis population served by Medicare's ESRD program, with an average annual growth rate of 15 percent in recent years (40). In 1974, people over 65 who were eligible for ESRD benefits by virture of Medicare enrollment made up less than 5 percent of the average annual enrollment (5); by 1979, patients over 65 accounted for over 20 percent and by 1984, patients over 65 accounted for over 25 percent of Medicare's ESRD program enrollees (40).

The unanticipated growth in ESRD program expenditures and the shifting demographic composition of the dialysis population have heightened concerns among some people that dialysis is being overused, that is, public resources are being misallocated, and/or dialysis treatment is being wasted on some patients for whom the benefits are questionable. The U.S. experience with dialysis is frequently cited by those who wish to warn against excessive growth in other disease-specific benefit programs or overuse of other life-sustaining technologies.

Because dialysis is usually life-sustaining, available, and currently reimbursed through Medicare's ESRD program, the dilemmas about whether to use dialysis in individual patients often center around the impact treatment would have on the patient's quality of life. Chronic dialysis imposes a strict regimen that demands time, limits travel, and imposes strict dietary requirements. Complications and frequent periods of illness and hospitalization are common. Still, most patients who accept chronic dialysis adjust successfully and are able to carry on their family and work roles. Some dialysis patients have survived for more than 20 years.

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[1] OTA acknowledges the important contribution in the preparation of this chapter of Nancy B. Cummings, M.D., Associate Director for Research and Assessment, National Institute of Diabetes, Digestive and Kidney Diseases.

Only limited information is available about how elderly patients adjust to chronic dialysis. However, the greater likelihood that elderly people will have comorbidities or reduced social responsibilities, compared with younger people, suggests that there may be important age-related differences in elderly patients' physiological and psychosocial responses to chronic dialysis. One study found that older patients generally reported a high degree of life satisfaction while undergoing chronic dialysis (49). Another study found, however, that withdrawal from dialysis was the most common cause of death in elderly dialysis patients, accounting for 40 percent of all deaths (compared with 22 percent for all ages) (16). The high rate of discontinuance may occur because the factors that trigger the decision, such as multiple underlying diseases, are more common and occur earlier in older dialysis patients than in younger ones (16).

While problems of access to ESRD treatment and personal financial hardship have been addressed to a very great extent through Medicare's ESRD program, fundamental problems related to decisionmaking for individual patients and related concerns remain. This chapter examines ESRD in the elderly population, the use, cost, and efficacy of various types of dialysis, the patients' experience, and how treatment decisions are made. It also discusses patient selection criteria and the influence of reimbursement on treatment patterns and quality of care for elderly patients.

DESCRIPTION OF DIALYSIS

Renal Failure: The Need for Treatment

Healthy kidneys regulate the body's internal environment of water and salts and excrete the end products of the body's metabolic activities and excess water (as urine). They also produce and release into the bloodstream hormones that regulate vital functions including blood pressure, red blood cell production, and calcium and phosphorus metabolism.

Impaired renal function, depending on its cause and severity, may affect any or all of these processes (see table 7-1). Impaired renal function may be due to problems in the kidney or to disease in other organs. It may be caused by pathological problems or normal, age-related processes.[2] It may be acute or chronic and either minor or life-threatening. All these distinctions are important determinants of prognosis and appropriate treatment.

When a person's loss of renal function is so severe as to be incompatible with life, the patient is said to be in *renal failure*. Renal failure may be either acute or chronic.

Acute renal failure is the sudden, potentially reversible loss of renal function. It may be caused by any of several hundred diseases, by drugs that are toxic to the kidneys, surgery, trauma, reduction or cessation of blood flow (i.e., ischemia) to the kidneys, or by obstruction of urine flow (13, 22). Many patients in acute renal failure regain natural function of the kidney after temporary support by dialysis. Others die from the underlying disorder that caused the kidney to fail. In some patients, acute renal failure is the precursor to chronic renal failure.

Chronic renal failure is irreversible, often progressive loss of kidney function. It can be caused by any of a large number of known and unknown factors, including immunological, congenital, or infectious diseases, or trauma to the kidneys. By far the most common cause of chronic renal failure among elderly dialysis patients in Medicare's ESRD program is hypertension (with heart and renal diseases). Other less common

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[2] Normal aging, in the absence of disease, is associated with a progressive loss of renal function beginning early in adulthood. On average, adults lose 7 to 8 percent of renal function per decade, but the individual variability in age-associated loss of renal function is very great. Some people lose as much as 60 to 70 percent between the ages of 30 and 80, and others experience little or no age-associated loss of renal function. Even when extreme, the normal changes in kidney function associated with aging do not significantly interfere with the normal volume and composition of body fluids or normal levels of waste products. Normal, age-related changes in renal function are significant, in general, because elderly individuals have lower reserve and are at heightened risk for developing renal failure as a result of disease or injury.

Table 7-1.—Functions of the Kidney and Their Alteration in Chronic Renal Failure

Function	Change in chronic renal failure
Excretion of water	Well-preserved in early chronic renal failure, progressively reduced in late chronic renal failure.
Excretion of water-soluble compounds	Varies with the compound; in general, progressively reduced as chronic renal failure progresses.
Production of erythropoietin (stimulates red blood cell formation)	Progressively reduced but not usually to zero; moderate to severe anemia.
Production of 1.25- and 24.25-hydroxycholecalciferol, the active forms of vitamin D	Reduced in moderate to severe chronic renal failure—reduced blood calcium and tendency to bone disease.
Production of renin—hormone which helps to maintain blood pressure and conserve sodium	Often increased—contributes to high blood pressure of chronic kidney disease; removal of both kidneys (to cure this) may cause low blood pressure.
Production of prostaglandins and intrarenal hormones	Uncertain what part changes in secretion of such hormones play in producing the symptoms of acute and chronic renal failure.

SOURCE: D.N.S. Kerr, "Renal Dialysis: Techniques and Clinical Applications," *The Oxford Companion to Medicine*, J. Walton, P.B. Beeson, and R.B. Scott (eds.) (Oxford, England: Oxford University Press, 1986).

causes of chronic renal failure in elderly people are glomerulonephritis, diabetic nephropathy, polycystic kidney disease, and pyelonephritis (1).

As defined in Medicare regulations, ESRD is the "stage of chronic renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life" (4). ESRD, with an accompanying syndrome called *uremia* (i.e., the symptomatic phase of renal failure), affects almost every system of the body, including the cardiovascular, respiratory, endocrine, central and peripheral nervous systems, the gastrointestinal tract, blood cells, skin, and bones. The symptoms often are so general that a diagnosis of kidney disease may not be clear. People experience an overall sense of feeling poorly, and they may have difficulty pinpointing the source of their malaise. The scientific understanding of all the ramifications of disorders of the kidneys is limited.

Disordered kidney function may be detected by simple laboratory tests such as urinalysis, measurement of blood chemistries (urea, creatinine, electrolytes, calcium, and phosphorus), and by determining the kidney's ability to clear standard substances from the blood.

Dialysis Procedures

ESRD can be managed by renal dialysis or reversed by a successful kidney transplant from a living or cadaveric donor (23). In special cases, other newer technologies such as hemoperfusion, hemofiltration, hemodiafiltration, and plasmapheresis may be used (1) (also see app. C, "Future Developments in Life-Sustaining Technologies").

For some patients, *kidney transplantation* is the preferred treatment. A successful kidney transplant can restore a patient to good health and a nearly normal lifestyle. The best results are obtained when the organ donor is a living, related donor, although good success is also achieved with cadaver kidneys.

Unfortunately, while transplantation is an attractive solution in principle, there are many difficulties in its implementation, especially the severe shortage of appropriately matched donor

Photo credit: Edmund G. Lowrie, National Medical Care, Inc

This 83-year-old woman has been on dialysis for 5 years.

kidneys (25). In addition, life-long immunosuppressive therapy, necessary to prevent rejection of the donor organ, has many deleterious effects. Because of these and other problems, kidney transplantation is not at present a realistic option for most ESRD patients. In 1985, only 9 percent of all ESRD patients received a transplant (42).

Kidney transplants are seldom performed in elderly people. In 1985, only 56 (1 percent) of the 6,938 kidney transplants performed in the United States were performed in patients aged 65 to 74 years, and only 3 were performed in patients 75 years and older (46). This apparent age-based rationing of kidney transplantation is usually explained on medical grounds. In particular, persons with vascular diseases (e.g., arteriosclerosis) are considered poor candidates for transplant surgery, and vascular diseases are common among elderly persons (13). Another medical factor that weighs against performing kidney transplants in some elderly persons is that they have multiple illnesses, which increase the risk of serious complications. Another serious problem is that age-related and other decreases in immune function heighten the risk of infection, especially with the administration of immunosuppressive agents that must be used to prevent rejection of the transplanted kidney.

How many elderly people might benefit from kidney transplantation if more donor kidneys were available is not known. At present, however, *renal dialysis* is the only widely used ESRD treatment for elderly persons. Therefore, renal dialysis is the focus of this chapter.

The term dialysis refers to any process in which the components of a liquid or solution are separated on the basis of the selective movement of different kinds of molecules through a semipermeable membrane. In the case of renal dialysis, impurities are separated from the blood and passed into a special fluid called the "dialysate" (or dialysis fluid) through a natural or artificial membrane. The movement of molecules through the membrane is caused by differences in concentrations of salts and toxic waste products in the blood and in the dialysate. Contact between the blood and dialysate is repeated many times, and the transfer continues until the two solutions have identical concentrations of the affected substances. Other components of the blood, like proteins and cells, cannot pass through the membrane and are retained in the blood.

The effectiveness of dialysis depends on both its duration and efficiency. The dialysis fluid, which is made up of the physiologically normal electrolytes found in blood plasma, is selected according to the approximate eventual composition desired in the plasma. When dialysis proceeds too rapidly, it may cause symptoms such as painful cramps or problems with blood volume. Because the specific treatment is determined based on experimentation, rather than theoretical knowledge, dialysis is said to be an "empirical" therapy.

Dialysis offers an effective artificial mechanism for performing kidney functions. Two main types of dialysis are available: 1) hemodialysis, and 2) peritoneal dialysis (including several variants of the latter).

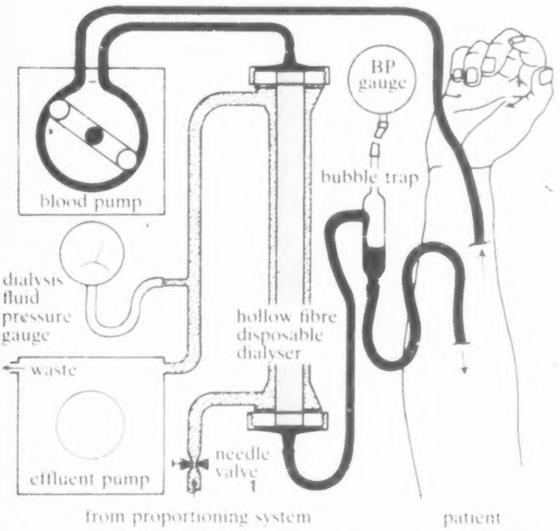
Hemodialysis

Hemodialysis is the oldest, most prevalent method of dialysis, and it is used today by the vast majority of ESRD patients in this country. It is the standard against which newer methods are judged. The first hemodialysis machine was developed in the Netherlands by Wilhelm Kolff during World War II. This "artificial kidney" and modifications of it permitted the first successful attempts to sustain patients with acute renal failure (1). Not until the 1960s, however, were there hemodialysis procedures to allow long-term *maintenance dialysis* of patients with chronic renal failure (1).

The process of hemodialysis involves pumping blood out of a patient's body into a dialyzer where impurities are removed, then returning the blood to the patient's body (see figure 7-1). For most ESRD patients using hemodialysis, treatments are carried out three times weekly for a duration of 3 to 5 hours each time. Some patients require more frequent hemodialysis, while some patients with significant residual kidney function can manage on fewer treatments per week. Hemodialysis may be conducted in a hospital, freestanding dialysis center, or in the patient's home.

Originally, hemodialysis required a new arterial and venous cut-down to obtain access to the patient's bloodstream for each dialysis treatment.

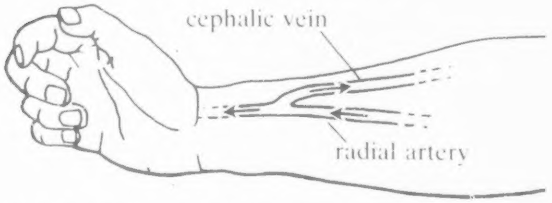
Figure 7-1.—Hemodialysis


blood pump
BP gauge
bubble trap
dialysis fluid pressure gauge
hollow fibre disposable dialyser
waste
effluent pump
needle valve
1
from proportioning system
patient

Blood is taken from the arterial tube and pumped through the hollow-fiber disposable dialyzer before returning through an air trap to the patient. Dialysis fluid flows in the opposite direction from a proportionating system, which makes it from water and concentrate. A number of safety devices (not shown) monitor the temperature, flow, and pressure of the dialysis fluid and the presence of air bubbles in the blood stream.

SOURCE: D.N.S. Kerr, "Renal Dialysis: Techniques and Clinical Applications," *The Oxford Companion to Medicine*, J. Walton, P.B. Beeson, and R.B. Scott (eds.) (Oxford, England: Oxford University Press, © 1986).

Figure 7-2.—Arteriovenous Fistula in the Arm of a Hemodialysis Patient



Arterial blood flows through the surgically created fistula into a superficial vein into which needles are inserted in the approximate direction of the arrow, identifying the cephalic vein.

SOURCE: D.N.S. Kerr, "Renal Dialysis: Techniques and Clinical Applications," *The Oxford Companion to Medicine*, J. Walton, P.B. Beeson, and R.B. Scott (eds.) (Oxford, England: Oxford University Press, © 1986).

The use of maintenance hemodialysis for patients with chronic renal failure was not possible until a Teflon arteriovenous shunt was developed by Scribner and his coworkers at the University of Washington in the early 1960s (1). Today, the standard blood access system for hemodialysis involves a surgically created connection between an artery and vein known as an arteriovenous fistula (see figure 7-2). Access to the fistula, which is usually in the forearm, is obtained by needle puncture. Developed in 1966, the arteriovenous fistula resolved problems that plagued patients with the arteriovenous shunt (i.e., clotting and infection) and offers a more permanent solution. Subsequent developments and refinements in the fistula have resulted in shorter dialysis time, increased safety, greater comfort, and economy. For patients whose veins do not permit the creation of a fistula, a variety of grafts are now possible; however, the "native" arteriovenous fistula is considered "the gold standard of blood access" (1). Consequently, one of the most important measures in the management of patients with chronic renal failure before they require dialysis is to preserve the forearm vessels so these can be used to develop a fistula when required (32).

Dialyzers consist of three parts: a compartment for the blood, a compartment for the dialysate, and a semipermeable membrane separating the two (30). The three principal types of dialyzers—hollow fiber, coil, and parallel plate—differ essentially in how these basic parts are arranged (30). All three types are described by manufacturers as "single-use disposables," but in fact are often reused (30). This practice of reprocessing and reuse, possible since the 1960s, has become widespread, but it remains controversial.[3]

Dialysate is usually prepared by diluting a commercially available concentrate with treated tap water. The specific composition of the dialysate reflects the needs of the individual patient and the choice of the physician.

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[3] In the late 1970s, there was a strong patient movement against dialyzer reuse in the United States, and the Senate Special Committee on Aging held hearings on the subject and produced a staff report on the subject (38). The effect of Federal policies on the practice of dialyzer reuse was reviewed in an OTA case study (30). Reuse is now very widely practiced worldwide (1). Under the 1987 budget reconciliation, the U.S. Department of Health and Human Services must establish, by Oct. 1, 1987, standards and conditions for safe and effective reuse and reprocessing of dialyzers (37).

Peritoneal Dialysis

The second major form of renal dialysis is peritoneal dialysis. First applied successfully in the treatment of acute renal failure in the late 1940s, peritoneal dialysis is a relatively simple technique whose use has increased for both chronic and acute care since the mid-1960s (1).

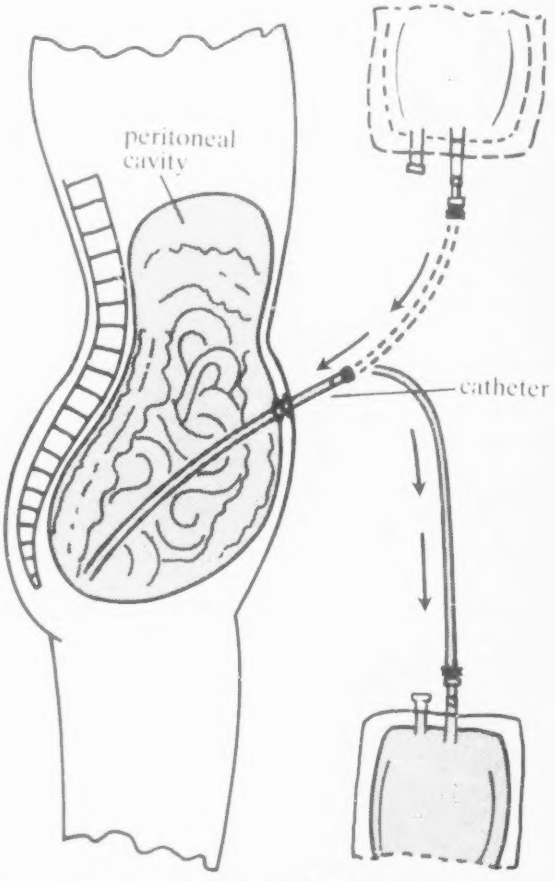
Peritoneal dialysis uses the patient's peritoneum (the semipermeable membrane surrounding the abdominal organs and lining of the abdominal cavity) to perform dialysis inside the patient's body. The standard blood access device is a permanent indwelling catheter with a long subcutaneous tract placed in the patient's abdomen. Sterile, warmed dialysis fluid is infused via the catheter into the patient's peritoneal cavity, allowed to remain there the prescribed length of time, then drained out along with the dissolved waste products, discarded, and replaced with fresh fluid. This cyclical process is continued for the appropriate number of instillations and removals. Solute removal occurs by diffusion from the blood in the peritoneal capillaries to the dialyzing solution. Solute removal depends on factors such as the dialysate flow rate, temperature, and pH. Fluid removal is by osmosis (1). Although peritoneal dialysis is much slower than hemodialysis, the same degree of correction occurs provided that longer peritoneal treatments are used.

Depending on the locale and timing of the procedure, chronic peritoneal dialysis may be intermittent (IPD); continuous cycling (CCPD); or continuous ambulatory (CAPD). Continuous peritoneal dialysis methods are typically used in the patient's home, while intermittent peritoneal dialysis is usually performed in a center or hospital.

Intermittent peritoneal dialysis involves the use of a machine to deliver sterile dialysate to the patient's peritoneal cavity and, after the prescribed dwell time, to remove the spent dialysate. The equipment is based on either a cycler that operates by gravity, a pump, or, in older equipment, a reverse osmosis process. Intermittent peritoneal dialysis is usually carried out for 10 to 12 hours, 3 nights weekly. The main problem with this technique is that as a patient's residual renal function declines, he or she require's longer treatment times.

CAPD, a technique of portable self-dialysis introduced in 1976, affords patients relative freedom and control over their own care, because it requires no machine and, often, no assistance (see figure 7-3). Self-care CAPD patients empty a 2-liter bag of dialysate into their peritoneal cavity and then proceed with their usual activities for the next 4 to 8 hours or overnight. At the end of the dwell time, the dialysate is drained into the empty bag, detached, and replaced by a fresh bag. The

Figure 7-3.—Continuous Ambulatory Peritoneal Dialysis (CAPD)



A sealed bag containing 2 liters of dialysis fluid is first emptied into the peritoneal cavity, then wrapped up and stowed in a pouch while the patient walks around, and finally hung below the abdomen to drain out the used fluid. The old bag is then changed for a full new one.

SOURCE: D.N.S. Kerr, "Renal Dialysis: Techniques and Clinical Applications," *The Oxford Companion to Medicine*, J. Walton, P.B. Beeson, and R.B. Scott (eds.) (Oxford, England: Oxford University Press, © 1986).

process of drainage, disconnection, connection, and infusion takes 30 to 45 minutes. The process is repeated three to five times daily, 7 days a week. Sterile technique must be maintained. CAPD has undergone an astonishingly rapid increase in use worldwide. It is now the most popular form of peritoneal dialysis and the most common form of home dialysis, accounting for over 13 percent of all dialysis patients in the United States (46). Apart from possible complications, one main problem with CAPD is that the patient has little or no respite from continuous treatment.

CCPD is a combination of intermittent peritoneal dialysis and CAPD that involves the use of a machine to cycle dialysate in and out of the peritoneal cavity automatically overnight and ambulatory peritoneal dialysis during the day (6). Typically, the dialysate is instilled into the peritoneal cavity in the morning and remains there until connection to the dialysis machine in the evening. CCPD reduces the need to make bag changes during the day and, by reducing the number of connections to a machine, may also lessen the risk of peritonitis (inflammation of the peritoneum).

Treatment Settings

The choice of treatment setting is closely related to the type of renal dialysis to be used. Both setting and type of dialysis depend on the patient's medical condition, ability to participate in care, level of support that the patient has available at home, resources in the community, and patient and caregiver preferences. Patients in acute renal failure are treated in hospital inpatient facilities, often in an intensive care unit (ICU). Patients with chronic renal failure can be treated in an ICU or a hospital inpatient facility, but if they are medically stable, they can receive dialysis in an outpatient facility (either a hospital-based outpatient unit or a freestanding dialysis center) or at home (1).

Institutions that provide outpatient dialysis for patients with chronic renal failure are divided by Medicare's ESRD program into two categories: hospital outpatient units and freestanding dialysis centers (1). Hospital outpatient dialysis units use the existing administrative structure of the hospital and are able to offer the usual range of hospital services, including diagnostic, therapeutic, and rehabilitative services. Freestanding dialysis centers provide staff-assisted outpatient dialysis but do not provide inpatient services (such centers usually contract with hospitals for necessary inpatient hospital services). More than 58 percent of the 1,558 institutions approved to provide outpatient chronic dialysis services in the United States are freestanding facilities (45).

Home dialysis involves training the patient and a family member, or in some cases a paid dialysis helper when a family member is not available, in order to assist the patient with dialysis at home (3). Home hemodialysis training takes from 3 weeks to 3 months, and home peritoneal dialysis training takes 1 to 2 weeks (1). Home dialysis gives patients with chronic renal failure a measure of independence and often reduces the cost of personnel (1). In general, however, home dialysis requires more patient initiative, responsibility, and better health. Home dialysis patients, because they are relatively healthy, have fewer hospitalizations than other dialysis patients and their annual total costs tend to be lower (39).

Home dialysis requires a range of support services on an ongoing basis. The patient should receive regular medical followup from a physician (usually monthly). Arrangements must be made for provision of supplies and maintenance and repair of equipment. Ongoing social work support, vocational rehabilitation services, and nutrition counseling are also important. The patient also must have contacts with appropriate members of a dialysis unit in case of an emergency. A nurse should be available on call at all times to answer questions or to respond in an emergency. In addition, self-care patients and their family members must be prepared for medical or mechanical emergencies.

Choice of ESRD Treatment Modality

In general, the least restrictive ESRD treatment modality that is medically appropriate should be the first choice. Thus, a chronic renal failure patient who is medically stable, instead of being confined to the hospital as an inpatient, should probably receive maintenance dialysis at a freestanding dialysis center or hospital outpatient unit. Similarly, a patient capable of home dialysis should be allowed that option because of the greater freedom it permits. Home dialysis places great responsibility on the patient. This is especially true for CAPD, which requires that the patient perform four or five treatments daily with meticulous attention to sterile technique (34).

Sometimes decisions about ESRD treatment modalities are limited by the availability of resources. Kidney transplantation, for example, depends on the availability of a living, related donor or cadaver kidney. Given the present shortage of donor kidneys, transplantation is not always an available option.

UTILIZATION AND COST OF DIALYSIS

Utilization of Dialysis

Medicare's ESRD program covers 93 percent of all patients with chronic renal failure in the United States (9),[4] and has made treatment for ESRD available to an increasing number of elderly and other Americans (see table 7-2).

In 1985, Medicare's ESRD program served a total of 90,621 dialysis patients and there were 6,938 transplants (46).[5] [6] Almost 31 percent of all dialysis patients in the Medicare ESRD program were over the age of 65 (46). Virtually all ESRD patients who are elderly when treatment is initiated are on dialysis.

The percentage of new dialysis patients who are elderly has increased faster than any other age group, with annual percentage increases from 1980 to 1984 of 11.7 percent for patients age 65 to 74 and 20.7 percent for patients over 75 (40). As evidence has accumulated that many elderly patients tolerate dialysis well and have a reasonable quality of life, more physicians recommend the therapy and more patients are willing to try it.

While elderly patients are undergoing dialysis in increasing numbers, they have not received treatment at the same rate as younger people. In 1979, while 80 percent of the patients age 25 to 45 at risk to die of uremia entered dialysis, only 30 percent of patients at risk over age 65 and just 6 percent of patients over age 75 did so (16).

The proportion of elderly ESRD dialysis patients will probably continue to increase for some time. This prediction is based on the aging of the U.S. population and the expectation that cadaver kidneys will become more readily available to younger ESRD patients (1).

One important implication of the increased enrollment of elderly persons in Medicare's ESRD program is an increasing proportion of patients with vascular and other comorbid conditions. Such conditions increase morbidity and reduce

Table 7-2.—Medicare ESRD Program Enrollment by Age, 1979-84

	1979	1980	1981	1982	1983	1984	Average annual percent increase	1983-84 percent increase
Total	54,428	61,899	70,435	77,886	86,499	92,770	11.3	7.2
Age:								
Under 25 years	4,145	4,552	5,023	5,406	5,817	6,025	7.8	3.6
25 to 44 years	15,325	17,108	19,745	21,694	24,070	26,070	11.2	8.3
45 to 64 years	23,561	26,351	29,844	32,773	35,330	36,991	9.4	4.7
65 years or over	11,397	13,888	15,823	18,013	21,282	23,684	15.8	11.3

SOURCE: U.S. Department of Health and Human Services, Health Care Financing Administration, Bureau of Data Management and Strategy, *Research Report: End-Stage Renal Disease, 1985* (Washington, DC: U.S. Government Printing Office, in press, 1987).

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[4] Persons covered by the armed services or by certain State or private insurance programs are exceptions (35).

[5] The total number of ESRD patients is not equal to the number of transplant patients plus the number of dialysis patients because dialysis patients may receive a transplant, a patient may receive more than one transplant, and a transplant patient may be returned to dialysis if the graft fails.

[6] The Veterans Administration, which has a high proportion of elderly male patients, had 3,327 dialysis patients in 1985 (40).

survival among patients receiving dialysis. Furthermore, since patients with such conditions are more likely to be hospitalized than patients without such conditions, their per capita costs are likely to be higher. It is uncertain whether all the patients with diabetic ESRD and all the elderly patients who might benefit from dialysis are being referred.

Growth in the overall U.S. ESRD dialysis population between 1980 and 1984, is shown in table 7-3. Growth in the overall population averaged approximately 10 percent per year. Growth in the number of patients using CAPD averaged almost 37 percent per year.

Cost of Medicare's ESRD Program

The economic burden of dialysis and kidney transplantation is great for the U.S. health care system and for patients and their families. Through Medicare, the Federal Government bears about 80 percent of the costs of treatment for ESRD. In 1984, ESRD beneficiaries represented less than one-third of a percent of all Medicare beneficiaries, and accounted for almost 3.2 percent of total Medicare expenditures (Parts A and B) (47,40). The costs of ESRD treatments not borne by Medicare are paid by private insurance, Medicaid, Federal programs such as those of the Veterans Administration, and/or personal resources.

The rapidly escalating expenditures of Medicare's ESRD program have been well documented (see table 7-4). In 1974, Medicare's ESRD program expenditures were $229 million for 16,000 beneficiaries. By 1984, there were 92,770 beneficiaries and annual program expenditures had reached almost $2 billion (40).[7] This escalation in aggregate Medicare expenditures for ESRD was not anticipated when Congress established the ESRD program in 1972. According to some observers, the cost figures Congress was given in 1972 were unreasonably low and quite misleading (25,29).

Because of the extraordinary costs of the ESRD program, Congress has sought to limit the expenditures through two laws: 1) the ESRD Program Amendment of 1978 (Public Law 95-292), and 2) the Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35). These laws contained, among other things, provisions designed to encourage home dialysis, which is less expensive than center dialysis, to encourage kidney transplantation, which, when successful, is less expensive over the succeeding years, and to establish composite reimbursement rates for ESRD services.[8]

Table 7-3.—End-Stage Renal Disease (ESRD) Dialysis Population by Type and Place of Dialysis, 1980-85[a]

Dialysis type/place	1980	1981	1982	1983	1984	1985	Average annual percent change	Percent change 1984-85
Total	52,364	58,924	65,765	71,987	78,483	84,797	10.1	8.0
In-unit hemodialysis	43,271	48,011	52,559	57,029	62,462	67,559	9.3	8.2
In-unit peritoneal	911	944	885	745	603	588	−8.4	−3.0
Home hemodialysis	4,715	4,481	4,394	4,323	4,125	3,983	−3.3	−3.4
Home peritoneal[b]	612	646	816	790	259	231	−17.7	−13.1
CAPD[c]	2,334	4,347	6,523	8,532	9,995	11,236	37.0	14.7
CCPD[d]	—	—	—	—	859	953	10.9	14.4
Self training	521	495	588	568	481	569	1.8	−48.6

[a] Counts are as of Dec[illegible] of each year from ESRD Facility Surveys.

[b] This figure decreased [illegible]gnificantly in 1984, partially due to CCPD patients being counted in this category in previous years. A CCPD category was added to the ESRD Facility Survey in 1984.

[c] CAPD. Continuous ambulatory peritoneal dialysis.

[d] CCPD. Continuous cycling peritoneal dialysis. CCPD rate of growth is calculated from 1984.

SOURCE: U.S. Department of Health and Human Services, Health Care Financing Administration, Bureau of Data Management and Strategy, *Research Report: End-Stage Renal Disease, 1985* (Washington, DC: U.S. Government Printing Office, in press, 1987).

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[7] HCFA data on reimbursements in the End-Stage Renal Disease Program include all Medicare reimbursements that pay for services used by this population, not only the cost of dialysis and transplantation.

[8] Provisions to encourage home dialysis in the ESRD Program Amendments of 1978 included a waiver of the usual 3-month waiting period for entitlement for patients in self-dialysis training programs, full coverage for home dialysis supplies, 100-percent reimbursement for home dialysis equipment, and authorization to establish target-rate reimbursements to encourage home dialysis. Provisions in the 1978 law to encourage transplantation included

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Table 7-4.—Medicare Reimbursements by Enrollees and Per Capita Reimbursements for Persons With End-Stage Renal Disease, 1974-84

Year	Reimbursements		Enrollment		Reimbursement per enrollee	
	Amount in millions	Percent change	Number in thousands	Percent change	Amount	Percent change
1974	$ 228.5	—	16.0	—	$14,300	—
1975	361.1	58.0	22.7	41.9	15,900	11.2
1976	512.2	41.8	28.9	27.3	17,720	11.4
1977	641.3	25.2	34.8	20.4	18,420	3.9
1978	800.0	24.7	43.5	25.0	18,390	−0.2
1979	1,010.7	26.3	54.4	25.1	18,579	1.0
1980	1,252.2	23.8	61.9	13.8	20,229	8.9
1981	1,476.2	17.9	70.4	13.7	20,969	3.7
1982	1,660.9	12.5	77.9	10.7	21,321	1.7
1983	1,893.6	14.0	86.5	11.0	21,891	2.7
1984	1,953.5	3.2	92.8	7.3	21,051	−3.8

NOTE: Data are incomplete for most recent years due to continual updating of the payment files.

SOURCE: U.S. Department of Health and Human Services, Health Care Financing Administration, Bureau of Data Management and Strategy, *Research Report: End-Stage Renal Disease, 1985* (Washington, DC: U.S. Government Printing Office, in press, 1987).

Even though Medicare's aggregate and per capita expenditures for ESRD have risen annually, when adjusted for inflation in medical care, the per capita expenditure rates have remained almost constant. As shown in table 7-4, average Medicare ESRD expenditures per capita rose from $14,300 in 1974 to $21,051 by 1984; when corrected for inflation, however, figures for the two years were virtually equivalent (29). Data from 1974 to 1979 show that while per patient costs for the ESRD program rose 30.8 percent, during the same period, national per capita health expenditures rose by 74.9 percent and the cost per day in community hospitals rose 91.4 percent (24). The average annual rate of growth in per enrollee reimbursement levels was less than 4 percent from 1974 to 1984 (40).

Treatment for patients on chronic renal dialysis includes the dialysis treatments themselves, physician services both for the supervision of dialysis and the treatment of other medical problems, any required hospitalizations, and ancillary services such as laboratory tests and medications (34). Reasonable estimates of the average annual costs of treatment of a patient on chronic dialysis range from $20,000 to $30,000 (1982 dollars) (34). Dialysis treatments themselves account for about 70 percent of this total.

The growth in aggregate Medicare expenditures for ESRD from 1974 to 1983 is primarily attributable to growth in the number of ESRD beneficiaries. From 1974 to 1981, about 76 percent of the growth in ESRD reimbursements was due to an increase in the number of beneficiaries (8).

Hemodialysis in hospital dialysis centers is the most expensive form of dialysis treatment (34). Differences in the cost of treatment by hemodialysis performed in independent centers, by hemodialysis performed at home, and by CAPD are sufficiently small that they can be accounted for by variations in methods used in available cost estimates and by case-mix differences (34).

Medicare approval of CAPD and the use of cyclosporin as an immunosuppressive agent for transplant patients may have a significant impact on the total costs of Medicare's ESRD program in the years ahead. Also, Medicare's Part A prospective payment system may shift some costs by encouraging transplantation and outpatient dialysis.

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extension of the post-transplant Medicare entitlement from 1 to 3 years, clarification of coverage for living-related donor costs, and of the reimbursement principles for cadaveric organ procurement.

The Omnibus Budget Reconciliation Act of 1981 directed the Health Care Financing Administration to develop reimbursement rates for dialysis treatment based on a composite of facility and home dialysis costs in order to provide an incentive for home dialysis. The new rates implemented in 1983 were $131 per dialysis treatment in hospital-based facilities, and $127 per dialysis treatment for freestanding facilities. These rates replaced the $128 previously applicable to both types of facilities. The act also had a further provision which made Medicare payment secondary to other insurance coverage for the first year following onset of chronic renal failure.

OUTCOMES OF DIALYSIS

Both the clinical and psychosocial outcomes of ESRD treatment are influenced by the cause of the kidney failure, comorbidity, type of treatment, and the willingness and ability of the patient to cooperate with the rigorous treatment regimen that dialysis entails. Specific information about the outcomes of dialysis in the elderly population is limited.

Clinical Outcomes

Survival

Survival rates among chronic dialysis patients appear to be related to a number of factors: age at the time of starting treatment, cause of renal disease, and presence of preexisting disease at the time of starting dialysis (1).

In general, survival rates are lower among elderly patients receiving chronic dialysis than among younger patients (2,33,49). In 1984, the 1-year survival rate for patients of all ages in Medicare's ESRD program was 84.8 percent. For U.S. dialysis patients between the ages of 65 and 74, the 1-year survival rate was 77.4 percent; for patients age 75 and over, it was 68.9 percent (table 7-5). For ESRD patients over age 65 treated with dialysis or transplant at the Northwest Kidney Center in Seattle, 5-year survival is 25 percent (1).[9]

The probability of survival while on ESRD treatment is closely associated with the primary cause of kidney failure. Patients with kidney failure caused by diabetic nephropathy[10] or primary hypertensive disease have worse survival than patients with other disorders (1). For dialysis patients in Medicare's ESRD program whose primary cause for kidney failure was diabetes mellitus, the 1-year survival rate was 74.6 percent in 1984; when hypertension was the primary cause of renal failure, the survival rate was 82.7 percent (see table 7-5).

Table 7-5.—Medicare ESRD Dialysis Patient Survival by Age and Cause of Renal Failure, 1980-84[a]

Characteristic	1980		1981		1982		1983		1984	
	Survival rate (percent)	Number	Survival rate (percent)	Number	Survival rate (percent)	Number	Survival rate (percent)	Number	Survival rate (percent)	Number
Total	86.0	33,206	85.5	38,345	85.7	43,324	85.1	47,708	84.8	51,788
Age adjusted total	86.0		85.9		86.5		86.3		86.3	
Age:										
0 to 14 years	96.3	286	96.8	334	97.7	379	98.9	394	96.6	419
15 to 24 years	96.0	1,729	96.9	1,878	97.7	1,941	97.1	1,975	97.4	1,828
25 to 34 years	95.0	3,776	94.4	4,240	94.7	4,665	95.1	4,878	94.9	4,919
35 to 44 years	91.3	4,823	91.3	5,330	92.2	5,865	92.7	6,343	91.7	6,820
45 to 54 years	89.1	6,863	89.0	7,590	90.0	8,346	88.8	8,910	89.1	9,255
55 to 64 years	83.7	8,582	83.4	10,020	83.6	11,496	83.2	12,807	83.6	14,037
65 to 74 years	77.0	5,769	76.6	7,040	77.0	8,169	76.8	9,383	77.4	10,795
75+ years	67.0	1,378	68.1	1,913	68.1	2,463	69.6	3,018	68.9	3,715
Cause of renal failure:										
Diabetes	76.4	1,800	73.9	2,248	76.6	2,880	73.4	4,149	74.6	5,616
Glomerulonephritis	90.5	5,228	89.8	5,893	89.9	6,458	89.2	7,646	87.6	9,379
Hypertension	85.2	3,765	84.2	4,541	84.0	5,388	83.4	6,972	82.7	9,074
Other/unknown	85.8	22,413	85.7	25,663	86.0	28,598	86.2	28,941	86.6	27,719

[a] Includes only persons who have survived for at least one year prior to January 1 of reference year

SOURCE: U.S. Department of Health and Human Services, Health Care Financing Administration, Bureau of Data Management and Strategy, *Research Report: End-Stage Renal Disease, 1985* (Washington, DC: U.S. Government Printing Office, in press, 1987).

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[9] The fact that survival rates for elderly dialysis patients are lower than those achieved in younger dialysis patients should not be used to argue against offering dialysis to elderly people. Older people in general are expected to die sooner than younger people. In fact, mortality data show that while older people on dialysis for ESRD have double the average projected 5-year mortality rate for their age group (70 percent compared with 32 percent), young people on dialysis for ESRD have 100 times the average projected 5-year mortality rate for their age group (25 percent compared with .25 percent) (15,21).

[10] Diabetic nephropathy is one of the most serious complications of diabetes mellitus, a multisystem disease that adversely affects the cardiovascular system with consequent complications of the heart and the blood vessels of the brain, the eyes, and the kidneys.

In 1985, the most common primary renal diagnosis for elderly dialysis patients who died was hypertension with heart and renal disease (in 35.7 percent of patients who died at ages 65 to 74 and in 35.7 percent who died at age 75 and over) (46). Diabetes mellitus with other complications was the second most common kidney diagnosis of ESRD patients dying between ages 65 to 74. Glomerulonephritis was the second most frequent diagnosis for those dying at age 75 and over.

The presence of preexisting disease is another factor that affects survival. Severe hypertension, cerebrovascular disease, cancer, and coronary artery disease have an adverse affect on survival rates (1).

In 1985, the leading cause of death among Medicare ESRD patients age 65 to 74 and age 75 and over was listed as "cardiac," accounting for 25 and 27 percent of deaths in the two age groups respectively (46). Myocardial infarction was the next most common cause of death for patients age 65 to 74, accounting for almost 15 percent of deaths. In the 75 and over age group, withdrawal from dialysis was the second most common cause of death, followed closely by myocardial infarction, with each accounting for about 12 percent of the deaths in that age group (46).

Complications and Morbidity

Patients receiving dialysis for chronic renal failure can experience problems ranging from life-threatening cardiovascular and cerebrovascular diseases to debilitating diseases of the bones or central nervous system, discomforts associated with local infections, and the need to replace catheters. These conditions can be caused by infections, metabolic changes, or mechanical problems with the dialysis equipment. Since elderly patients are more likely than younger patients to suffer from multiple health problems, they face an increased risk of developing complications.

Some problems are associated with particular forms of dialysis or dialysis settings. Problems associated with peritoneal dialysis, for example, include mechanical problems such as perforation of the bowel (1). Peritoneal dialysis is also associated with a high risk of peritonitis (i.e., inflammation of the peritoneum). The latest U.S. data on CAPD show an infection rate of slightly more than one episode per year of treatment (35). If detected and treated early, peritonitis often can be treated at home and rarely causes death. If peritonitis recurs, however, it can eventually force the patient to change to hemodialysis.

Problems associated with hemodialysis include complications related to the vascular access site. These include prolapse or obstruction of the catheter or shunt and thrombosis of the arteriovenous fistula. Replacement or transfer of the fistula to another site may be required, and eventual depletion of convenient anatomical sites may necessitate changing to another mode of treatment. Access problems are especially likely in older patients with arteriosclerotic vessels and in diabetics (34). In dialysis centers, outbreaks of viral hepatitis are a serious threat to both patients and staff. Use of the recently developed hepatitis-B vaccine is beginning to affect the rate of hepatitis B infection, but other forms of hepatitis still occur (1). The development of cardiovascular morbidity including myocardial infarctions, cerebrovascular accidents, and advanced peripheral vascular disease may result from preexisting disease, but the pace of these disorders may be accelerated by hemodialysis (34).

Chronic renal failure is almost always associated with anemia, and this is a major factor in a lack of well-being felt by many dialysis patients (1). In most patients, anemia is due to reduced production of erythropoietin by the kidney causing a reduction in red blood cell production (10). Erythropoietin can now be made with recombinant DNA techniques, and clinical trials with synthetic erythropoietin have reduced patients' anemia. (See app. C, "Future Developments in Life-Sustaining Technologies.) Patients who have normal iron stores when they begin dialysis typically develop iron deficiency within 6 months to 2 years (1). Once this occurs, it may be treated by oral iron supplements or other methods.

Other conditions associated with dialysis include bone diseases, which occur because of derangement in the metabolism of calcium and phosphorus, and peripheral and central nervous system problems. A syndrome known as dialysis encephalopathy which includes personality changes and an abnormal electroencephalogram and progresses to death within a few months, has been linked to the accumulation of aluminum in the blood and tissues (1).

The major problem affecting long-term survival among dialysis patients is cardiovascular disease (1). Plasma lipid abnormalities and hypertension can contribute to cardiovascular diseases. Parathyroid gland disorders and sexual dysfunction also can occur.

Various measures can be taken to prevent and reduce the complications and morbidity associated with dialysis. Among these measures are controlling hypertension, screening and vaccinating for hepatitis, rigorously controlling diet and fluid intake, and meticulously caring for the shunt or catheter site.

Elderly patients as a group tend to have more chronic diseases than younger patients, and these can affect the outcome of dialysis. Diabetes mellitus, for example, is not only a cause of kidney disease, but may be accompanied by many complications other than those related to the kidney. Degenerative joint disease poses difficulties in mobility, which can interfere with a patient's commuting to the dialysis center or his ability to manage self-dialysis. Varying degrees of cognitive impairment, from mild changes related to cerebral arteriosclerosis to major problems caused by Alzheimer's disease, can interfere with a patient's ability to cooperate with the necessary therapeutic regimen including diet, control of fluid intake, as well as the dialysis. When lethal diseases such as metastatic cancer are present in tandem with ESRD, they raise difficult ethical questions about the value of continued dialysis.

Psychosocial Outcomes

Maintenance dialysis introduces major difficulties into the lives of patients with ESRD. The commitment to time-consuming, regular treatments demands that patients order their lives around a rigid schedule. Dietary and fluid restrictions must be carefully followed and travel must be carefully planned. In addition to the more serious complications associated with dialysis, wide swings in blood pressure, weakness, and nausea are common discomforts.

ESRD patients on dialysis must adjust to the idea of continued treatment for the remainder of their lives and the ever-present risk of complications related both to their renal failure and to dialysis itself. For those patients who are dialyzed in any type of center, there is the additional problem of commuting to and from the center. Transportation may pose a great burden for some elderly persons.

Some of the chronic stresses associated with ESRD include dependency on medical machinery and personnel, the constant threat of death and of reduced life expectancy, and decreased physical strength and stamina. Some researchers have reported feelings of helplessness and depression among some dialysis and transplant patients (7). A variety of losses frequently accompany ESRD treatment and can add to the emotional strain. These include the loss of participation in valued activities such as work, family and household responsibilities, and leisure activities. These intrusions threaten the individual's security and enjoyment of life and may contribute to a sense of loss of control and reduced self-esteem.

Adjusting to a technology-dependent lifestyle can be very difficult. Information about the psychosocial effects of dialysis, especially for elderly patients, is limited, but some evidence suggests that elderly patients tolerate dialysis as well as, or better than, many younger dialysis patients (16,49).

A national survey completed in 1985 collected data on, among other things, how dialysis and kidney transplant patients perceived the quality of their lives (12). The data represented a balance of geographic locations, type of facility, ownership, size, academic affiliation, availability of a home training program, number of patients by type (home, in-center, CAPD/CCPD, transplant), and service area. Although the data are not representative of the entire population of dialysis and transplant patients in the United States, the information provides insights not available from other sources.

Special analyses done for OTA provide some age-group comparisons (11). Of the 859 patients responding to the survey, about 13 percent were age 65 or older. More than half of these elderly patients were between the ages of 65 and 69; half as many were patients age 70 to 74; and the rest were age 75 or older. Elderly patients (age 65 and over) represented approximately 21 percent of in-center hemodialysis patients, 10 percent of home hemodialysis patients, and 15 percent of CAPD patients. None of these elderly patients had received a transplant.

In comparison with younger patients, ESRD patients age 65 or over had a higher well-being index, more positive feelings, less negative feelings, and a feeling that their life was easier (11). They had greater satisfaction with life in general and, in particular, with their marriages, family life, savings and investments, and standard of living. On the other hand, elderly respondents assessed their own health as poorer than that of others their age. They reported greater functional impairment, markedly less ability to work, and a much lower current employment rate than younger patients. Respondents under and over age 65 revealed generally small differences in the "total sickness impact profile." Elderly respondents reported a reasonable degree of ability to perform normal activities. A detailed analysis of overall functional status, using the Karnofsky Index (18), showed that almost half (47 percent) of the elderly patients fell in the top three categories: "normal" (2.7 percent), "normal activity" (24.3 percent), and "normal activity with effort" (23.4 percent).

Two smaller studies also provide some information on patients' satisfaction with their lives on dialysis (26,31). One study focused on ESRD patients as a whole and the other compared patients between the ages of 55 and 65 with patients who were 65 or older. In both studies, the vast majority of respondents said their lives were worth living, dialysis was worthwhile, and the future would be better than the present or the past. Ten percent of respondents age 55 to 65 and 20 percent of those over age 65 reported that they had considered withdrawing from dialysis treatment. Also, respondents' self-assessments of their overall health, the number of hospital admissions, and effectiveness of treatment (as measured by blood chemistries) were very similar for these two age groups.

Another measure of the psychosocial impacts of dialysis is the extent to which patients decide to discontinue treatment. National data indicate that in 1985, 8.5 percent of patients age 65 to 74 and 12 percent of patients over age 75 died as a result of "withdrawal from dialysis" (46). Withdrawal from treatment was the third most common cause of death among elderly dialysis patients.

A retrospective study of 1,766 patients in the dialysis program of the Regional Kidney Disease Center in Minnesota found that in 155 cases, dialysis was stopped before a biologic cause of death supervened (27). In one study that asked questions about the quality of life, 10 percent of respondents age 55 to 65 and 20 percent of those over age 65 reported that they had considered withdrawing from dialysis treatment (31). While suicide among dialysis patients is thought to be high, statistics on actual or contemplated "withdrawal" cannot be equated with suicide. Some of these cases involve patients whose will to live may be great, but for whom further treatment would be futile. Others are no longer mentally capable and the decision to withdraw dialysis is made by a surrogate.

MAKING DECISIONS ABOUT DIALYSIS

Decisions about starting and stopping dialysis exemplify many of the dilemmas that attend decisions about the use of life-sustaining technologies for elderly people. Among the criteria considered in these decisions are those that pertain to the patient and those that relate to the availability of resources. These two types of criteria are sometimes interdependent. When resources are scarce, it may be that only those patients for whom significant medical benefit is most certain will receive treatment. In times of greater abundance, the pool of treatment recipients may expand to include patients for whom the chance of significant improvement is smaller. Sometimes in fact, the pool may expand to include patients for whom treatment offers no real hope of benefit.

For over a decade after it was technically possible to provide chronic dialysis and/or kidney transplantation for ESRD patients, the scarcity of resources and high cost of the treatment placed it out of reach for most Americans. Patient selection committees were burdened with weighty decisions about who should live. The criteria they used to select patients for treatment included, in addition to medical and psychological criteria, the criterion of social worth. Discussions might focus on factors such as the social value of the patient to the community, the family responsibilities of the patient, and the patient's employability. In 1972, however, Congress acted to include payment for ESRD treatment under Medicare, and these agonizing deliberations over patient selection were ended.

Policymakers in the United Kingdom have taken a dramatically different approach to the allocation of ESRD treatment resources (see box 7-A). In the United Kingdom, "the fear of treating too many inspires greater passion than the fear of treating too few" (14).

In both the United States and the United Kingdom, how ESRD patients are chosen for treatment and which treatments they receive are determined at least as much by social priorities as by medical appropriateness. The difference in the two countries, representing two extremes of the range of patient enrollment, are accounted for at least partly by their difference in ability and willingness to make or avoid "tragic choices." As long as funding is available for ESRD treatment through

Box 7-A.—Treatment for ESRD in the United Kingdom

The United Kingdom and the United States have responded to the problem of treating ESRD patients with opposite approaches. The United Kingdom has one of the lowest treatment rates in the western world. Its enrollment rate for ESRD is only 29.7 patients per million population per year, a sharp contrast to the 38 to 47 per million population per year enrolled annually in other European countries. Between 3,000 and 5,000 people die of untreated renal failure each year in Great Britain (14). In addition to the differences in numbers of patients treated, there are differences in the choice of treatment modality. In the United Kingdom, the vast majority of treated patients receive transplants or home dialysis. In other European nations, this group is only 20 to 33 percent of the total.

The United Kingdom's policy was developed in the early 1960s by physicians' committees that were constituted by the National Health Service, Britain's national health care system. It was based on three fundamental assumptions. The first assumption is that budget allocations are never to be exceeded. The United States' policy, on the other hand, is that when the funds for Medicare are exhausted, they will be supplemented. While U.S. officials "know only with hindsight what they have spent . . . U.K. officials have a clear idea before the fact" (14). This strict adherence enforces the rationing of resources.

The second assumption in the United Kingdom is that value must be obtained for money spent. This concept is applied equally to all types of public spending; the National Health Service is no exception. The value obtained must be returned to the body whose money is spent, i.e., society. On this basis, treatment selection criteria include employability and age. This rationing seems "not only sensible but necessary—in a patently obvious way" (14).

The third and final assumption is that patients in the United Kingdom are not entitled to treatment. The fact that a reliable life-saving treatment exists does not imply that a person who will die without it has a right to receive it. British policymakers use the American experience to justify this position.

> . . . that ESRD patients ought legally to be entitled to treatment, however, is regarded by U.K. policy makers with a mixture of contempt and horror. Indeed, it is the American experience which is looked to as a cautionary example. In interview after interview, both administrators and physicians decried it as medically absurd—with tales of senile patients with metastatic cancer being dialyzed—and financially "out of control," attributing it to naively idealistic Congressmen and greedy proprietary dialysis center owners. America, it was always pointed out, was wealthy enough to afford such foolish extravagance; the U.K. was not (14).

Medicare's ESRD program, at least some tragic choices can be avoided.

Decisions About Initiating Dialysis

With payment for ESRD treatment widely available through Medicare's ESRD program, decisions about initiating dialysis in the United States can focus on considerations pertaining to the individual patient. One potential consideration is whether dialysis will provide medical benefit to the patient. Determining the likelihood of medical benefit from dialysis involves assessing a patient's medical status and prognosis. This involves the assessment of systems involved in the patient's renal disease, as well as any concomitant medical problems. Another potential consideration in decisions about initiating dialysis is the patient's ability and willingness to cope with strict treatment regimens. In some cases, the presence of a condition such as cancer may lead to a decision not to initiate dialysis. The following case describes an elderly man who was unwilling to undertake chronic dialysis treatment:

> **A 77-year-old man of sound mind had known for many years that he had progressive kidney disease. Conservative management of his disease had prolonged his life for a year or more free of artificial life support, but during the course of the year, he began to experience early symptoms of kidney failure. He and his wife considered a trial of dialysis therapy which could prolong his life, but he decided to accept the natural course of his affliction and stated he did not want this type of treatment. Having exercised his freedom of choice, the man seemed content. He called the kidney staff occasionally to inquire about new symptoms, but seemed to accept his situation, even when informed that the end would come within months (13).**

Decisions About Stopping Dialysis

In some cases, a point may be reached where dialysis appears to be of no further medical benefit, where a patient does not wish to continue, or when a surrogate decision is needed. This point may come in a matter of weeks or after many years of dialysis treatment.

Decisions to discontinue dialysis are often more difficult than decisions to start dialysis. The following case illustrates some of the decisionmaking dilemmas that can arise:

> **Mr. B was a retired minister, age 71, when dialysis was started. For 5 years, he remained an active participant in his social environment, church activities, and of the community of dialysis patients in his unit. Longstanding arthritis required him to use a cane and slowed his ambulation, but Mr. B enjoyed his social contacts, had a home in an apartment complex for the elderly, and complied with his medical regimen.**
>
> **During his fourth year on dialysis, Mr. B had an upper gastrointestinal hemorrhage, was critically ill for 1 day, and required intensive care for the subsequent 3 days. Throughout the hospitalization, he appeared to be mentally sluggish and depressed. He ate poorly and did not speak with the staff. His dialysis was continued. Dialysis patients whom he knew visited him, and his mental state brightened. After several days, he was discharged from the hospital and returned to his previous schedule, although he seemed to be slower and to have occasional lapses of memory. He appeared for his dialysis treatments on schedule, but because they perceived deterioration in his functioning, the renal staff discussed his condition with his family.**
>
> **One year later at age 76, Mr. B suffered a cerebral thrombosis that left him partially paralyzed, unable to speak, and confused. Dialysis was continued for 2 weeks with no measurable improvement. At this point, although the staff was not certain that he understood, they advised him that dialysis was of no further benefit. The family, when given the same information, was disturbed by the recommendation to discontinue treatment and felt that the staff was "pulling the plug." The staff assured the family that they were not being asked to make the decision but to be aware that it was the staff's medical judgment that further dialysis would not be beneficial to Mr. B. After further discussions with the family, who recalled Mr. B's vigor and fear of being an invalid, agreement was reached. Mr. B remained quietly in the hospital for a few days and died uneventfully (13).**

Strong Memorial hospital, the tertiary care center for the Rochester, New York area, deals with decisionmaking dilemmas for some dialysis patients by offering patients a trial treatment period at the end of which the decision to withdraw dialysis may be considered (13). A trial treatment period allows a patient (and family) an opportunity to "try out" dialysis without making an irreversible decision. It also gives physicians time to establish a more precise diagnosis, adjust therapy to an optimal level, and better assess prognosis.

A 69-year-old widowed woman with a history of high blood pressure, adult-onset diabetes, and several heart attacks had begun maintenance dialysis 6 months before being transferred to Strong Memorial Hospital. In the hospital, she was restricted to bed because of her heart disease, which caused chest pain with minimal exertion and shortness of breath. After diagnostic studies, her dialysis treatments were altered to minimize the fluid overload affecting her heart, and her medications were adjusted to improve her heart function. During the first week in the hospital, the medical team of cardiologist, nephrologist, dialysis nurses, social workers, and others discussed her medical, personal, and social situation with the patient and her daughter and son-in-law.

When it was evident to everyone that the likelihood of improvement was nil, the concept of a trial of maximum therapy for a finite period was raised first with her daughter and son-in-law, and then with the patient. These interactions were delicate and sensitive. The patient accepted the concept of a trial of intensive therapy with the understanding that a complete reevaluation of her status would be made after 4 weeks of intensive therapy.

At the end of a month, she was unable to move out of bed without experiencing severe chest pain and shortness of breath. The daughter's home situation was considered excellent, the son-in-law was supportive of his wife's caring for her mother, and privately, the two volunteered jointly that the patient would be accepted with loving care in their home. The patient was informed that there was little hope for improvement in her condition. Later in the conversation and according to plan, the patient and physician were joined by the daughter and her husband in order to assure the patient that they understood her problem and wanted her to come home with them. The woman decided that she would be more comfortable in her daughter's home for her last few weeks. The emotions of this discussion were intense and everyone had tears on their cheeks. The patient died 19 days after discharge from the hospital, in her daughter's home (13).

Although older patients in general report a high degree of life satisfaction while undergoing chronic dialysis (49), they do withdraw from dialysis at higher rates. In one study, withdrawal was the cause of death in 40 percent of elderly people compared with only 22 percent for all ages (16). The high rate of discontinuance may occur because factors that can trigger the decision, such as multiple underlying diseases, are more common and occur earlier in dialysis in older patients (16).

The study of 1,766 ESRD patients at the Regional Kidney Disease Center in Minnesota between 1966 and 1983 (27) cited previously found that dialysis was discontinued in 155 patients of all ages. These 155 patients represented 9 percent of the 1,766 patients who received treatment and 22 percent of all deaths. The investigators concluded that "stopping treatment is a common mode of death in patients receiving dialysis, particularly in those who are old and those who have complicating degenerative diseases" (27). Dialysis was discontinued in 1 of every 11 patients and in 1 of every 6 over age 60.

Notes describing the competence of patients from whom dialysis was withdrawn were found in 132 charts. Half (62) of these patients were said to be "competent," and of these, 58 made the decision to withdraw on their own. In the 64 patients deemed "incompetent because of dementia, strokes, or coma" the decision to withdraw dialysis was made by a surrogate. In all the "incompetent" patients and a majority (61 percent) of the "competent" patients, a new medical complication preceded the decision to withdraw dialysis. Brain disease was the most common complication leading to withdrawal of dialysis. Of the 155 patients, 44 had dementia. The majority of all patients who discontinued dialysis were on in-center dialysis (73 percent). The mean treatment period among patients from whom dialysis was withdrawn was 30 months; only 10 percent of patients had been on dialysis as long as 3 years. Mean survival after dialysis stopped was 8.1 days. Of the 155 patients who stopped dialysis, 45 had diabetes. In all age groups except the oldest, dialysis was stopped three to five times more often among diabetic patients. Among nondiabetic patients, degenerative diseases such as heart and vascular disease, cancer, and chronic pulmonary disease were significantly more common in patients from whom dialysis was withdrawn than in patients who remained on dialysis.

The site of residence could be ascertained for 98 of the 155 patients. At the time a decision to discontinue dialysis therapy was made, 81 percent of these patients lived at home. At the time of death, however, most of the patients who discontinued dialysis were in hospitals. A small percentage died at home (13 percent) or in hospices (4 percent).

Decisionmaking Procedures

Initially, ESRD therapy is considered by a patient's physician, either a family physician who refers the patient to a nephrologist or a nephrologist who has followed the patient with renal disease for a long time and recognizes that the disease has reached the stage where dialysis and/or renal transplantation should be considered. In some centers, especially the larger ones, a review committee meets regularly to consider the treatment to be recommended for each new ESRD patient—the different types of dialysis, a kidney transplant, as well as a recommendation not to treat at all. Such committees usually include representatives from among the following fields: nephrology, transplantation, urology, nursing, social work, clergy, law, hospital administration, nutrition, and the dialysis center staff. Often, the patient and/or patient's family are asked to attend so they can understand and participate in the decisionmaking process and ask questions of the health team.

There is almost nothing in print about the criteria dialysis centers use to select patients for dialysis. In January 1984, the Section on Renal Disease, Department of Internal Medicine, University of Arizona Health Sciences Center, prepared a written policy in preparation for a site visit by the Joint Commission on Accreditation of Hospitals. This policy, outlined below, is representative of the approach described to OTA by many nephrologists responsible for dialysis patients. Chronic dialysis therapy is provided to every patient, regardless of age, who:

1. grants fully informed consent;
2. has chronic, irreversible ESRD;
3. has a reasonable expectation of a quality of life acceptable to himself or herself; and
4. desires and can cooperate with such therapy (48).

One study of the criteria used by physicians to select patients for ESRD treatment at 373 dialysis centers and 80 transplantation hospitals (20) rated potential patient selection criteria along a 5-point scale to indicate their importance in decisionmaking. Virtually all respondents considered the following criteria important: prognosis, psychological stability, and likelihood of medical benefit. A very large majority (nearly 90 percent) of respondents said they would consider the patient's willingness to participate in treatment and/or consider the patient's age in decisions about treatment. Only 10 percent of responding dialysis facilities said they currently excluded patients because of advanced age, but 85 percent of dialysis centers reported that "under conditions of significant scarcity," they would do so.

There is no uniform mechanism for making decisions to withdraw dialysis. Although most physicians consider it their responsibility to make recommendations about appropriate medical care for patients, the ultimate decision about discontinuing treatment usually rests with the patient or patient's family (27). The case of 78-year-old Earle Spring highlights the legal, ethical, and medical issues that can surround decisions about the termination of dialysis for patients who are no longer decisionally capable (see box 7-B).

Ethical Issues

According to some people, because the ESRD program covers treatment costs for virtually all ESRD patients regardless of age, diagnosis, or any other factor, there is a strong financial incentive to provide treatment for all patients who reach ESRD, and to continue that treatment as long as it is able to sustain life (25). In some cases, however, the initiation or continuation of dialysis (or other life-prolonging treatment) may be a burden to the patient.

Any analysis of ethical issues surrounding decisions about initiating and terminating dialysis treatment must recognize that Western culture and the United States place great weight on the importance of the individual and the right of self-determination or autonomy. When possible, the patient must be allowed to decide if a commitment to long-term dialysis is worth the trade-off. As discussed throughout this report, medical staff and patients often will differ significantly in what they perceive about quality of life. Some patients with ESRD are incapable of making their own de-

Box 7-B.—The Earle Spring Case

In October 1977, Earle Spring, 78, was diagnosed as having chronic organic brain syndrome by a psychiatrist. In November of the same year, he suffered a minor scratch on the instep of his foot. This rugged outdoorsman eschewed physicians and hospitals and left his scratch untreated until his foot had become gangrenous. He was hospitalized, then developed pneumonia and kidney failure. Dialysis was initiated, and Spring improved but required three 5-hour dialysis sessions per week. His mental deterioration became more pronounced. After more than a year of treatment, the nephrologist informed Spring's son Robert that his father was not benefiting from dialysis. He suggested that initiating dialysis for a man Spring's age might have been a mistake and that it would be best if the treatment were ended. The son and the wife agreed with the physician and requested that the treatments be stopped.

Because of the Massachusetts Supreme Judicial Court's 1977 *Saikewicz* ruling (36), decisions of such significance have to be made by the courts rather than by families and physicians. Robert Spring, who had been appointed temporary guardian, petitioned the Franklin County Probate Court for an order to terminate the dialysis treatments. An attorney *ad litem* to represent the best interests of the patient, Mark I. Berson, insisted that the court could not render a "substituted judgment" without some evidence from Spring's lucid moments on the subject. On May 15, 1979, Judge Keedy entered a judgment permitting Robert Spring "to refrain from authorizing further life-prolonging treatment" for his father. Berson was not satisfied and appealed. Judge Keedy then entered a new order stating that Spring's wife and son, together with the attending physician were to make the decision. Berson appealed again. The Court of Appeals upheld the probate court's action and rejected Berson's position on the need for an express statement of intent to withhold treatment. On January 10, the Supreme Judicial Court heard the case and concluded that the trial judge's finding, that if Earle Spring were competent he would not choose to receive life-prolonging treatment, was correct. Spring's guardian was directed to refrain from authorizing any further life-prolonging treatment for his father.

The staff at the Holyoke Geriatric Center was appalled over the decision to stop dialysis treatment. Two nurses on the 3-11 shift asked Spring if he wanted to die and he reportedly replied, "No." A psychiatrist had previously evaluated Spring as incompetent, but the nurses, taking his statement as proof of Spring's desires, brought the story to the local newspaper which used it as headline news. Berson replied immediately. On the basis of an affidavit by a right-to-life group, he petitioned Judge Keedy to reinstate dialysis treatments until new evidence of Spring's competence could be gathered. Right-to-life activists hired a lawyer to petition the probate court to admit them as parties to the case. Judge Keedy denied the petition to reinstate dialysis treatment. Berson appealed again and the appeal was granted by the Supreme Judicial Court which appointed five psychiatrists and geriatric specialists to determine Spring's mental status. During that time, Spring was admitted to the hospital and diagnosed as having infection and pneumonia. He responded to medical treatment and was returned to the nursing home in an extremely weakened condition. The day before the competency hearing was scheduled, Spring died. The next day, the five court-appointed physicians filed their report: Spring "was suffering from such profound mental impairment that he had no idea where he was or what was going on. The dementia was not related to the kidney failure, was untreatable, and irreversible." Had he not died the day before, the responsibility for deciding to stop dialysis treatments would have rested where it had 14 months previously—with the court.

SOURCE: J.J. Paris, "Death, Dying and the Courts: The Travesty and Tragedy of the Earle Spring Case," *Linacre Quarterly* 49:26-41, 1982.

cisions about dialysis treatment, and the decisions have to be made by a surrogate.

Legal Issues

A 66-year-old widow had been on maintenance dialysis for 8 years. In 1978, she had a stroke that left her left side paralyzed. In 1983, she had another stroke that left her with a right-sided paralysis, unable to communicate or to perform the simplest task. Her heart was unstable and she required monitors and other resources available only in the medical ICU. All medical professionals involved in caring for the patient agreed that the patient's outlook for recovery and return to a meaningful existence was hopeless, but three of her sons were adamant that every possible treatment be provided. Without the consent of the legal next of kin, no one felt that it was ethically or legally right to discontinue treatment. The patient remained hospitalized, mostly in the ICU for 69 days. She died of overwhelming infection, dialyzed until the day before her death (13).

Few legal cases have arisen as a result of ESRD treatment or decisions. One reason for this may be that dialysis centers are particularly cautious not to deny treatment if the patient and/or family insist on receiving dialysis, even though the kidney team recommends against it. The University of Rochester kidney team has commented that if there is a potential for litigation, patients will continue to receive dialysis even if the kidney health care team believes treatment should be stopped (13). Similar statements have been made by dialysis team leaders across the country. Leroy Shear, Director of the Western Massachusetts Kidney Center noted, "The way I practice medicine is very much determined by what the courts tell me to do" (17,28).

FINDINGS AND IMPLICATIONS

An increasing number of elderly patients with ESRD are being treated by dialysis. Almost half the new patients starting treatment in the United States are age 55 or older, and almost half the patients enrolled in Medicare's ESRD program are 55 or older (1). These numbers will probably continue to increase (1). Experience has shown that elderly patients tolerate dialysis reasonably well, and with resources and payment now available through Medicare's ESRD program, age is not a prominently used criterion in the selection of patients.

The American experience with dialysis for ESRD presents two major concerns: 1) the high costs of dialysis borne by the Federal Government, patients, and their families; and 2) ethical problems accompanying the decisionmaking process involved with starting and stopping dialysis treatment.

Through Medicare, the Federal Government bears about 80 percent of the cost of treatment for ESRD for about 103,000 patients (44). As noted earlier, the cost of Medicare's ESRD program is now well over $2.1 billion annually, and aggregate expenditures have been increasing each year. Increases in aggregate expenditures are due largely to growth in the ESRD population. Despite the fact that Medicare's ESRD population includes a higher percentage of older and sicker patients, per capita expenditures (when adjusted for inflation) have remained fairly constant or even decreased over the life of the program (25).

In part because there are Medicare funds available to cover treatment, dialysis for ESRD is currently available to Americans of all ages. Although elderly people as a group tend to have more complications and lower survival rates than younger people, a patient's age alone is not a good predictor of the outcome of dialysis. Other important considerations include the cause of a patient's renal failure and the presence of comorbidities.

Typically, a decision to initiate dialysis involves a recommendation from the health care providers involved in a patient's care. Increasing emphasis is placed on the importance of patient autonomy, however, and major efforts are made to inform patients and their families about all aspects of their disease and treatment. In some cases, patients may decide that they do not want dialysis treatment even if it may prolong their lives.

For some patients, a point may be reached where dialysis is no longer beneficial. When a recommendation is made to discontinue dialysis therapy, agreement is sought from the patient or, if the patient is incapable of participating, from the patient's next of kin. In the absence of clear permission from either the patient or surrogate, fear of litigation sometimes keeps kidney care teams from discontinuing dialysis even when it is no longer medically beneficial.

Many elderly patients with ESRD have been restored to productive and meaningful lives through dialysis treatment. Others are able to enjoy a quality of life that they find acceptable. Some elderly patients, however, choose to discontinue dialysis.

Clearly, the ethical decisions associated with dialysis and its dilemmas must be approached individually. The solutions to the critical dilemmas associated with ESRD and dialysis, however, may have important implications for other catastrophic illnesses and life-sustaining technologies.

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Chapter 8

Nutritional Support and Hydration

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Chapter 8

Nutritional Support and Hydration

INTRODUCTION

Nutritional support and hydration are the most controversial of the life-sustaining technologies discussed in this report. Most recent court cases concerning life-sustaining technologies involve nutritional support and hydration, and decisions about withholding or withdrawing these technologies evoke a strong response in many people.

Nutritional support can be provided by either of two methods:

- *enteral or tube feeding procedures* in which nutrients and water are infused into the patient's stomach or intestine via tubes,[1] or
- *parenteral feeding procedures* that include any method other than enteral but are primarily intravenous procedures in which nutrients and water are infused into the patient's veins via catheters.

For people who are unable to swallow, digest, or absorb adequate amounts of food and fluids taken by mouth, these procedures can be life-sustaining.

Total parenteral nutrition (TPN)—an intravenous procedure that supplies sufficient nutrients to maintain a person's normal weight and growth for a prolonged period—was first demonstrated in the late 1960s, and its use has increased dramatically in the past decade. The use of tube feeding has also increased as a result of improvements in materials and formulas and increased interest in nutritional support in general due to the development of TPN (54).

Without questioning the value of nutritional support procedures in general, this chapter addresses four questions about their use for some elderly people:

- Are they used inappropriately for some terminally ill or severely debilitated elderly people for whom they may simply prolong suffering?
- Are they denied to elderly people who would benefit from them?
- How are decisions made about their use, and what role do the patient and family have in the decisionmaking process?
- What is the quality of nutritional support treatments for elderly patients?

Answers to these questions require a synthesis of information from three perspectives that are described below: 1) the ongoing debate about withholding and withdrawing nutritional support and hydration that has been the province of legal and ethical scholars but increasingly involves health care providers and the public; 2) the medical specialty, clinical nutrition, that is the province of nutritional support specialists—physicians, dietitians, nurses, and pharmacists who provide nutritional support; and 3) the growing field of aging and nutrition that is primarily the province of research clinicians. This chapter draws from all three perspectives as they relate to treatment decisions for elderly people.

PERSPECTIVES ON NUTRITIONAL SUPPORT AND HYDRATION

The Debate About Withholding and Withdrawing Nutritional Support and Hydration

Although physicians have made decisions about withholding and withdrawing nutritional support and hydration for many years, the legal and ethical issues involved in withholding and withdrawing these procedures have been publicly debated only in the past few years. Several factors may account for this change. Increased use of the procedures has resulted in greater public awareness of the decisionmaking dilemmas they sometimes raise. Since the procedures are covered by Medicare and Medicaid for many patients, their increased use has also led to concerns about increased public expenditures. Media coverage of court cases involving nutritional support has also resulted in greater public awareness of decisionmaking dilemmas. In recent years, there has been increasing debate about withholding and withdrawing other life-sustaining technologies, such as dialysis, resuscitation, and mechanical ventilation, and some people think that the current focus on nutritional support is just the next step in this progression. Finally, it has been suggested that since nutritional support and hydration are the only procedures keeping some comatose and severely debilitated patients alive, the current debate may reflect a realization that stopping them is perhaps the only way to allow these patients to die (42,205).

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[1] Enteral nutrition is sometimes defined to include oral nutritional supplements, but in this report, the term "enteral" refers only to tube feeding.

People tend to have intense and divergent beliefs about the appropriateness of withholding and withdrawing nutritional support and hydration. Some people believe that these procedures should almost never be withheld or withdrawn from any patient. Others believe equally strongly that they can and should be withheld from some terminally ill, comatose, and/or severely debilitated patients. Although such patients are often elderly, the debate about withholding and withdrawing nutritional support and hydration is by no means restricted to elderly people.

One point of disagreement in the debate is whether tube and intravenous nutrition and hydration should be considered medical interventions (like the other life-sustaining technologies discussed in this report) or basic supportive or nursing care. People who consider them medical interventions usually argue that they can be withheld or withdrawn in some cases. People who consider them basic supportive or nursing care often argue that they should be withheld or withdrawn only from patients whose death is imminent or for whom it is not medically possible to provide them.

Another point of disagreement in the debate is whether withholding or withdrawing nutritional support and hydration from a terminally ill or severely debilitated patient is killing or merely allowing the patient to die. Some people argue that since all human beings must have food and water to survive, withholding or withdrawing tube or intravenous nutrition and hydration is tantamount to killing the patient. Others argue that withholding or withdrawing them simply allows death to occur as a result of the patient's underlying illness.

A third point of disagreement concerns patient suffering. Some people emphasize patient suffering caused by malnutrition, starvation, and dehydration.[2] Others emphasize patient suffering associated with aspects of tube or intravenous feeding procedures (e.g., insertion of the tube or catheter or physical restraints that may be used to keep the patient from pulling it out) and suffering related to the continuation of life for patients with intractable pain, severe disability, or very poor quality of life.

A confounding factor in the debate about withholding and withdrawal is the symbolic nature of nutritional support and hydration. Giving food and water is a fundamental aspect of caring for another person, as reflected in the cultural, religious, and moral traditions of our society and the earliest relationship of parent and child. Failure to provide food and water—even when it requires tube or intravenous procedures—is deeply troubling for many people (45).

For this and other reasons, some ethicists who believe that it is sometimes permissible to withhold or withdraw other life-sustaining interventions are hesitant or opposed to ever withdrawing nutritional support and hydration (42,131,192). Some health care professionals share these attitudes. A study of physicians, nurses, and social workers who care for elderly patients (231) found that, on average, individuals in each profession were more uncomfortable about withholding tube feeding and intravenous hydration than resuscitation, antibiotics, and other life-sustaining treatments.

The debate about withholding and withdrawing nutritional support and hydration is not over. It remains a difficult dilemma with important clinical, legal, ethical, financial, and political aspects. This chapter does not attempt to resolve the debate but rather presents information about the procedures and the factors that affect decisions about their use.

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[2] Malnutrition is any disorder of nutrition due to unbalanced or insufficient diet or defective assimilation or utilization of nutrients. Starvation is long, continuous deprivation of food. Dehydration is the loss of body water in excess of intake and may be due to decreased intake or increased loss (25).

The Perspective of Nutritional Support Specialists

Nutritional support specialists focus on clinical aspects of the procedures. They emphasize the positive, therapeutic, and sometimes life-saving effects of nutritional support and hydration and point out that treatment decisions for most patients do not involve complex legal and ethical considerations. In the view of some nutritional support specialists, the most serious concern about the procedures is not questions about withholding and withdrawal but rather problems that restrict their use, including lack of awareness of their therapeutic potential and limited third-party reimbursement.

The debate about withholding and withdrawal focuses on patients who are terminally ill, comatose, or severely debilitated. In contrast, nutritional support specialists focus primarily on patients who are critically ill or physically unable to swallow, digest, or absorb food or fluids taken by mouth. This difference in focus partially explains differences in attitudes toward the procedures. It is important to note, however, that the two groups of patients are not mutually exclusive, and some patients—e.g., severely debilitated patients who are also critically ill and terminally ill patients who cannot swallow, digest, or absorb food or fluids taken by mouth—can correctly be placed in both groups. In fact, some of the most difficult decisions about nutritional support and hydration concern precisely those patients.

The difficulty of determining which patients are terminally ill—a problem that is noted throughout this report—may be of particular concern in decisions about the use of nutritional support and hydration. Health care providers and others differ in their awareness of the potential therapeutic effects of these procedures. Thus, nutritional support specialists, who are particularly aware of the relationship between disease, nutritional status, and treatment outcome, may sometimes correctly classify patients as critically ill but potentially responsive to treatment, when other health care providers, families, and others may incorrectly believe that the same patients are terminally ill.

The meaning of the term "responsive to treatment" is often unclear in discussions about nutritional support and hydration. While some people consider all patients who are kept alive by nutritional support as responsive to treatment, others say that some comatose, terminally ill, and severely debilitated patients are not responsive to treatment and that their dying has merely been prolonged. Depending on the viewpoint of the observer, therefore, the same patients could be considered either responsive or not responsive to treatment.

Careful use of the terms "responsive to treatment," "critically ill," "terminally ill," "comatose," and "severely debilitated," is particularly important, though frequently lacking, in debate about nutritional support and hydration (88,111). The uncertainties involved in defining the terms and classifying individuals in these categories, however, must be recognized.

Special Considerations in the Use of Nutritional Support for Elderly Patients

A large proportion of the people receiving nutritional support and hydration are elderly, but there has been relatively little attention to the special needs of elderly patients. Changes in body composition, metabolism, and nutritional requirements associated with normal aging are documented in a growing volume of research (55,140,213). Yet little is known about adjustments in nutritional formulas or techniques that may be needed for elderly people and possible differences in the efficacy of these procedures for younger v. older people.

Assessment of nutritional status of elderly people may be difficult because many assessment techniques used with younger people rely on physiological characteristics that are affected by aging. Yet nutritional standards for the elderly have not been established. Without agreed upon standards, it is difficult in some cases to determine whether nutritional support is needed.

Several other problems complicate decisions about nutritional support and hydration for elderly patients. A significant but unspecified number of elderly people on nutritional support are confused. Such patients may be unable to participate in decisionmaking. Moreover, because confused patients often try to pull out feeding tubes or catheters, a decision to use nutritional support may imply that physical restraints will also be required. It is also particularly difficult to determine whether severely confused patients are suffering as a result of treatment or, conversely, lack of treatment.

Some elderly patients who receive nutritional support, including many of the confused individuals described above, are nursing home residents. Treatment decisions for these patients are complicated by the fact that some nursing homes are not adequately staffed to provide the skilled care that nutritional support patients need. Each of these problems is discussed at greater length in this chapter.

DESCRIPTION OF NUTRITIONAL SUPPORT AND HYDRATION

The Need for Nutritional Support and Hydration

People who do not take in adequate amounts of food and fluids will eventually die of malnutrition and dehydration or complications of these conditions. Malnutrition is a disorder caused by inadequate intake of calories, protein, carbohydrates, fats, vitamins, minerals, trace elements, or any combination thereof. The effects of malnutrition depend on its severity and duration and which specific nutrients are lacking. In general, however, the effects include weight loss, listlessness, and depression; decreased ability to resist infection, to recover from illness, and to withstand surgery or other treatments; impaired wound healing; decreased cardiac and respiratory muscle strength, confusion, coma, and eventual death (115,139,143,203).

Dehydration, the loss of body water in excess of intake, is caused by decreased fluid intake or inability to conserve fluids as a result, for example, of renal disease or severe diarrhea. Dehydration results in dry mucous membranes; decreased sweat, saliva, and tears; muscle weakness, rigidity, or tremors; confusion, hallucinations, and delerium; abnormal respiration; coma; and eventual death. Reduced body water also alters the concentration of electrolytes such as sodium and potassium, with severe and sometimes life-threatening consequences (210).

People with a variety of conditions are at risk of malnutrition and dehydration. Although some conditions that cause malnutrition or dehydration occur more often in elderly people than younger people, none is unique to elderly people.

People who are physically unable to swallow, digest, or absorb food and fluids taken by mouth are at obvious risk of malnutrition and dehydration. This group includes:

- people who are comatose;
- people who are physically unable to swallow;
- people who have an obstruction of the gastrointestinal tract;
- people who are unable to eat following gastrointestinal surgery; and
- people with acute or chronic diseases that cause inability to digest or absorb nutrients.

Without tube or intravenous feeding and hydration, such people will become increasingly malnourished and dehydrated. As their immune function is reduced, they may die from infections before death can occur from malnutrition or dehydration.

Critically ill patients who are physically able to swallow, digest, and absorb at least some food and fluids taken by mouth may also be at risk of malnutrition and dehydration. Malnutrition in some critically ill patients is caused by anorexia (decreased appetite) associated with certain diseases, such as cancer. In addition, many acute and chronic diseases and treatments such as surgery increase the body's requirements for nutrients; if intake is not increased correspondingly, malnutrition can develop rapidly (115).

Some people are malnourished and dehydrated prior to becoming critically ill. Their malnutrition and dehydration may be due to physical, psychological, or social factors that affect their eating habits, i.e., poor dental status, decreased mobility, social isolation, confusion, poverty, or depression (53,75,137). Moreover, it is likely though not proven, that nutritional reserve capacity decreases as people age. As a result, elderly people may be more susceptible than younger people to malnutrition when their dietary intake is decreased (115).

Critically ill patients who are malnourished can be given oral nutritional supplements if they are able to swallow, digest, and absorb adequate amounts of food and fluids taken by mouth. If not, such patients require tube or intravenous feeding.

People who are too weak to feed themselves or who have neurological diseases that make them unable or unwilling to feed themselves are also at risk of malnutrition and dehydration. Most of these people can be hand fed. Hand feeding is time-consuming, however, and it has been alleged that some hospitals and nursing homes use tube feeding because sufficient staff time cannot be allocated to hand feeding. The use of tube feeding for this reason is generally frowned on, and there are no data to indicate whether or how often it occurs.

Photo credit: Gretchen Kolsrud

A nursing assistant hand feeds a severely debilitated elderly patient

Some patients cannot be hand fed because they have difficulty swallowing—a condition sometimes associated with stroke and other neurological disorders—and may choke while being fed. Other patients refuse to open their mouths, spit out food, or take in food and fluids so slowly that they cannot be hand fed an adequate diet on a long-term basis, even by a willing and devoted caregiver. The following case illustrates this problem:

> **Mrs. G had been a picky eater all her life, but 4 months after she was admitted to a nursing home, she stopped eating almost entirely, although she continued to drink small amounts of liquids. Mrs. G had been somewhat confused for several years: she knew her name and recognized regular staff but could not remember their names or where she was. For 2 weeks after she stopped eating, staff sat beside her at meal times, trying to get her to eat something. There had been no observable change in her physical or mental condition. In response to questions, she said that she would eat, that she was not sick or in pain, and that she liked the food. But she did not eat.**
>
> **Eventually, the doctor ordered nasogastic tube feeding. Mrs. G said she did not like the tube. She turned her head when the nurse tried to put it in, and as a result, she had to be held still by a nursing assistant. Every time the tube was put in, she pulled it out. Her hands were wrapped in gauze, put in thick, quilted mittens, and tied to the bed rails, but she still managed to get the tube out.**
>
> **Staff continued to try to get her to eat enough so that tube feeding would not be needed. One evening, a nurse sat with her for an hour, during which time she drank 8 oz. of an oral nutritional supplement, about 200 calories, one tiny sip at a time. To take in adequate nutrients, she would have to continue at that rate for at least 8 hours a day—obviously an impossible expectation.**

Little is known about elderly people who do not feed themselves and refuse hand feeding or about people who eat too little to live. For the woman in the case just cited, encouragement, supportive listening, and a comprehensive medical examination may provide some clues about a solution to the problem. If that fails, there are only two choices—tube or intravenous feeding against the patient's will or gradually worsening nutritional status and eventual death.

Techniques for Nutritional Support and Hydration

All nutritional support specialists that OTA consulted in the preparation of this report stressed that tube and intravenous procedures are only part of a range of nutritional support options that also includes well-planned meals and oral nutritional supplements. The following discussion focuses on tube and intravenous procedures because they are the subject of clinical, legal, and ethical debate and raise the most difficult treatment questions.

In general, tube feeding is used when the patient's gastrointestinal tract is capable of digesting and absorbing food normally. Intravenous techniques are used when the gastrointestinal tract is blocked or when disease interferes with digestion and absorption of food and fluids.[3] The nutritional support techniques described below are used for patients of all ages. Few adjustments have been made in devices, techniques, or formulas for elderly people. The procedures are described in some detail, because debate about their use often centers on questions about whether they are medical interventions or basic supportive or nursing care and whether their use entails patient suffering.

Tube Feeding Techniques and Associated Risks

Feeding tubes are placed through the patient's nose or a surgical opening into the gastrointestinal tract. Different tube feeding routes are illustrated in figure 8-1. Table 8-1 describes placement procedures, indications for use, and associated risks of each.

Rapid infusion of enteral formulas into the gastrointestinal tract can cause regurgitation, aspiration, vomiting, or diarrhea. Conversely, very slow infusion can result in inadequate nutrition and hydration. In the past, the usual method of infusion was bolus feeding in which the formula is administered in a single dose using a large syringe. For many patients, this method causes diarrhea and other symptoms associated with too rapid infusion (44,176). Another method is gravity drip, in which the formula container is hung above the patient and a regulator clamp controls the flow rate. With gravity drip, hourly monitoring of the flow rate by a nursing attendant, family member, or the patient is necessary (155). Even hourly monitoring may be insufficient, however, since flow rate using the gravity drip method can change by as much as 50 percent in an hour (92).

Enteral feeding pumps assure a uniform infusion rate and lessen the problems associated with too rapid or too slow infusion. Pumps are not always used, however, sometimes because of lack of third-party reimbursement.

Most enteral formulas are bought premixed, although blenderized table food is sometimes used. Premixed formulas vary from those with standard ingredients to those with a defined chemical composition tailored to a specific metabolic disorder. No enteral formulas have been developed specifically for elderly people, although some nutritional support specialists and formula manufacturers are considering developing such formulas (58).

Special formulas for patients with kidney, liver, and respiratory diseases are used for some elderly patients with these diseases. Clinicians disagree, however, about the merits of special formulas (33). Industry representatives have told OTA that some hospitals that were buying special formulas prior to 1983 are now buying more of the standard formulas that are significantly cheaper, probably as a result of cost-containment measures imposed by Medicare and other third-party payers (113).

Recently developed modular formulas allow the combination of individual nutrients to meet the specific needs of each patient and offer an alternative to premixed formulas. Some experts are optimistic about the use of these formulas for critically ill patients (33). Others believe that they will not be widely used because of the staff time required for mixing them and because of the availability of a large variety of premixed formulas (92).

Enteral formulas provide an excellent medium for proliferation of bacteria that can cause diar-

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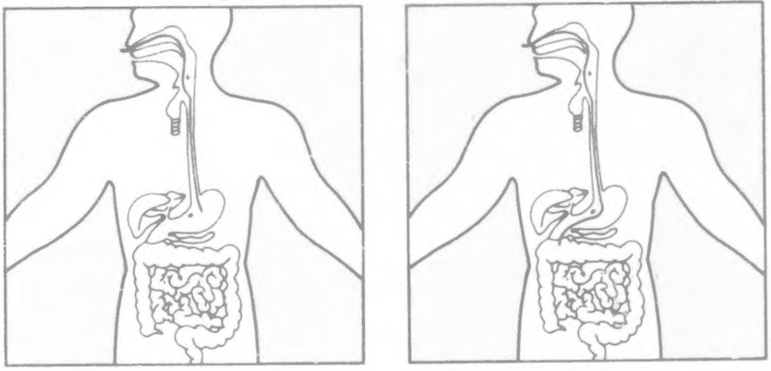
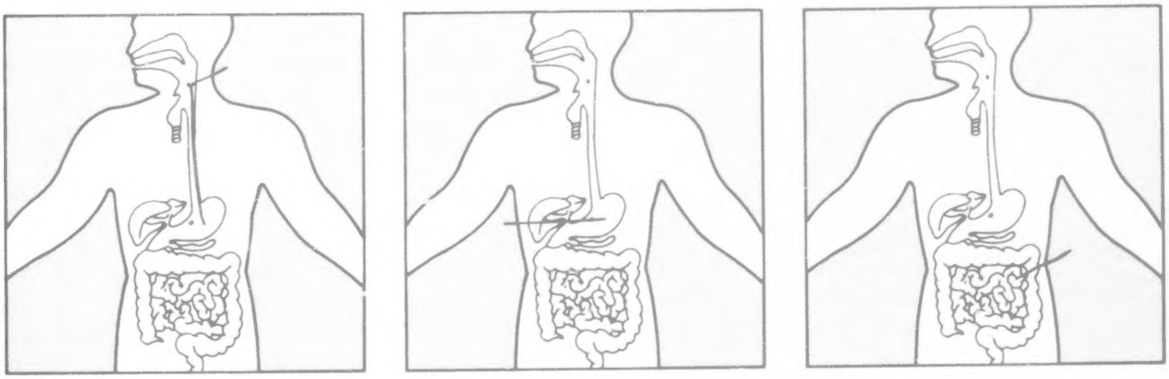
[3] Both tube and intravenous techniques are sometimes referred to as *hyperalimentation*, a term that is not used in this report.

Figure 8-1.—Tube Feeding Routes



Nasogastric tubes are placed through the nose, down the esophagus, and into the stomach.

Nasoenteral tubes are placed through the nose, down the esophagus, through the stomach, and into the duodenum (first loop of the small intestine) or jejunum (second loop of the small intestine).



Pharyngostomy and esophagostomy tubes are placed through the neck, into the throat or upper esophagus, and into the stomach.

Gastrostomy tubes are placed through the abdomen into the stomach.

Jejunostomy tubes are placed through the abdomen into the small intestine.

SOURCE: Adapted from Ross Laboratories, *Tube Feeding: Clinical Application* (Columbus, Ohio, 1980) reprinted with permission.

rhea, enteritis, and bacteremia (3,15,47,76,183). Enteral infusion times range from 1 to 24 hours a day. If the formula is infused over many hours, special equipment must be used to protect it from airborne contaminants and to keep it cool in order to limit the growth of any organisms (155).

Beyond the Food and Drug Administration's basic "food manufacturing procedure" requirements, there are no Federal regulations for the manufacture or marketing of enteral formulas. The number of companies that manufacture these formulas has increased greatly in the past few years. Claims made for specific formulas by manufacturers are frequently not documented, and there are no regulatory mechanisms to ensure the safety, quality, or suitability of formulas for their intended use. In contrast, infant formulas are highly regulated. Although beyond the scope of this report, a thorough review of the safety and quality concerns related to these products is needed.

Nasogastric tubes are used much more often than any other enteral procedure. In one New Jersey hospital, for example, 89 percent of tube-fed patients had nasogastric tubes (185). One reason for the relatively wide use of nasogastric tubes is that physicians generally consider such tubes "noninvasive," meaning they do not require surgery and can be inserted by a person with little training. Often in the context of ethical and legal debate, nasogastric tubes are similarly referred to as "noninvasive." In this context, the term noninvasive often seems to suggest that nasogastric tubes are not burdensome. From the patient's point of view, however, they can be burdensome, as discussed below.

Nasogastric tubes are recommended for short-term use. Yet many elderly patients, especially those in nursing homes, are fed through nasogastric tubes for prolonged periods, up to several years. Alternatives to nasogastric tubes for long-term use are pharyngostomy, gastrostomy, and jejunostomy tubes. Although use of these tubes is "invasive" in the sense that at least minimal surgery is required, and each entails risks for the patient, many physicians suggest that they are more comfortable for long-term use than nasogastric tubes and that confused patients are less likely to try to pull them out (39,123,125,129,202). Research is needed to evaluate these alternatives in terms of patient comfort and potential risks, especially for confused patients who need long-term nutritional support.

Table 8-1.—Tube Feeding Techniques: Placement, Indications for Use, and Associated Risks

Nasogastric tubes may be placed by a physician, another health care professional, the patient, or a trained family member. The position of the tube must be tested before each feeding, because the tube can be mistakenly placed in the patient's lungs; if food or fluids are put in the tube while it is in the patient's lungs, severe respiratory distress will occur, potentially causing death. Other risks of nasogastric tube feeding include irritation of the nose, throat, and esophagus, and aspiration, a condition caused by regurgitation of the stomach contents into the lungs.

Nasoenteral tubes are usually placed by a physician or a specially trained nurse and must be tested every few days by a trained health care professional or by X-ray. These tubes are recommended for short-term use in patients for whom regurgitation and aspiration are likely or whose stomach or upper intestinal functions are impaired.

Potential problems include the difficulty of passing the tube through the pylorus (the small opening at the lower end of the stomach) and laceration of the pylorus or other parts of the gastrointestinal tract if the tube is removed too rapidly. In addition, feeding into the duodenum and jejunum tends to cause diarrhea.

Pharyngostomy and esophagostomy tubes must be surgically placed by a physician. Esophagostomy tubes are seldom used now. Pharyngostomy tubes are recommended for long-term use because they do not irritate the nose and throat like nasogastric and nasoenteral tubes. Potential problems include aspiration, scarring of the insertion site, and swallowing difficulty.

Gastrostomy tubes are placed by one of two methods. Surgical placement, that is always by a physician, is done with a local, spinal, or general anesthetic. A newer method, percutaneous endoscopic placement, does not require surgery or general anesthetic. Gastrostomy tubes are recommended for long-term use and when swallowing is impaired as a result of obstruction or neurological disease.

Potential problems include aspiration, skin irritation around the tube site, and displacement of the tube into the abdominal cavity. In addition, the small balloon that is sometimes used to hold the gastrostomy tube in place can obstruct the pylorus and interfere with gastric emptying.

Jejunostomy tubes are surgically placed. These tubes are recommended for long-term use or when there is a problem with gastric emptying or regurgitation. Potential risks include skin irritation around the tube site, clogging, displacement of the tube, and diarrhea.

SOURCE: Adapted from Oley Foundation, "Nutritional Support and Hydration for Critically and Terminally Ill Elderly," prepared for the Office of Technology Assessment, U.S. Congress, Washingto , DC, November 1985.

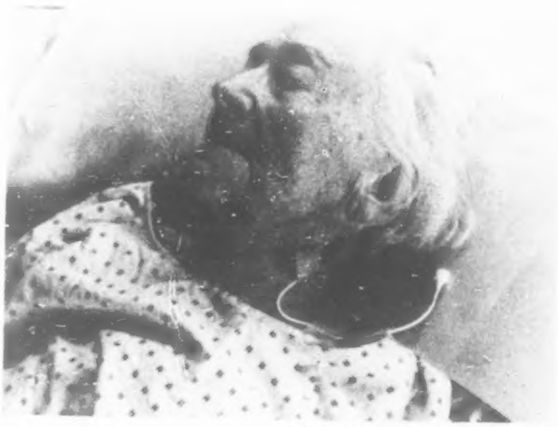


Photo credit: Robert B. Gilsdorf, M.D.

For long-term use, a pharyngostomy tube, as shown here, may be more comfortable than a feeding tube that passes through the patient's nose.

The Patient's Experience of Tube Feeding

The patient's experience of tube feeding varies greatly depending on the type of tube and the patient's physical and mental condition. Insertion of a nasogastric or nasoenteral tube is uncomfortable for many conscious patients who gag as the tube is put down the throat. For confused patients, insertion of the tube can be frightening and frequently requires that the patient be physically restrained (121,125). Insertion of pharyngostomy, esophagostomy, gastrostomy, and jejunostomy tubes generally requires surgery that is frightening for some patients and entails some postsurgical discomfort.

Nasogastric and nasoenteral tubes can cause irritation of the nose and throat and difficulty swallowing (125,129,137,187,223). Some patients and families object to the appearance of the tube in the nose. However, patients are able to talk, and some can eat or drink small amounts by mouth depending on their physical condition (176). Feeding tubes are generally left in place between feedings, but some patients learn to insert a nasogastric tube themselves, and they may insert and remove it for each feeding.

Many patients who require short-term tube feeding are critically ill and are undergoing concurrent medical treatments, all of which cause varying degrees of discomfort. For them tube feeding may be no more burdensome than the other interventions. Some patients may be so sick that they are only partially aware (if at all) of the feeding tube.

Many elderly patients who receive long-term tube feeding are confused, so it is difficult to determine how they feel about the treatment. Confused patients often try to pull out feeding tubes, especially nasogastric tubes. Some observers believe this behavior indicates that the tube is irritating. Others believe that these patients are too confused to notice the tube and that pulling at it is just restless, meaningless behavior that is characteristic of some confused patients. In many hospitals and nursing homes, patients who pull out their feeding tubes have their hands put in mittens and tied to the sides of their bed or chair to prevent the behavior (118,121,125). Although anecdotal evidence suggests that this practice is widespread, there are no data on the percentage of tube fed patients who are physically restrained.

Intravenous Feeding Techniques and Associated Risks

The most commonly used intravenous feeding techniques are: 1) total parenteral nutrition (TPN), in which a formula capable of maintaining the patient nutritionally for a prolonged period is infused into a vein—usually a large, central vein in the patient's chest; and 2) the well-known intravenous procedure in which water, saline or glucose solutions, and medications are infused into

Photo credit: [illegible]

This hospital patient who is receiving nasogastric tube feeding is also able to eat small amounts of food normally.

a small, peripheral vein—usually in the patient's arm. The nutrients that can be provided by the latter method are inadequate to sustain life for prolonged periods, although the procedure is frequently used to maintain hydration in critically and terminally ill patients and others. The following discussion refers only to TPN.

TPN catheters are usually placed in large, central veins because most TPN formulas are highly concentrated and can cause inflammation, occlusion, or clotting in small veins with low blood flow. In high-flow, central veins, the TPN formula is rapidly diluted (72). Figure 8-2 shows a typical TPN placement.

For TPN, a constant and accurate infusion rate is critical, and a variety of pumps are currently available with special features including a battery to ensure that power failure does not interrupt infusion and alarm devices to warn nursing attendants or patients about air in the catheter or occlusions (i.e., resistance to flow that could mean a kink in tubing or a clot) (155).

TPN formulas are individually mixed to match the nutrient and fluid requirements of the patient and modified as the patient's needs change. Laboratory tests are used to monitor the accuracy of the formula. Table 8-2 presents a standard formula. This formula would be modified, for example, for a patient with renal failure to restrict sodium, potassium, magnesium, and phosphorus—minerals whose excretion is defective in renal impairment (155). For most elderly patients, the volume of fluid, 3 liters in table 8-2, should be decreased (50).

TPN patients of all ages are highly susceptible to infection because of malnutrition and acute and chronic diseases. In addition, some TPN formulas provide an ideal growth medium for certain contaminating organisms, and TPN catheters are often left in place for a prolonged period. These factors create a serious risk of catheter-related infection (26,111,155). Some research indicates that such infections occur more often among TPN patients over 60 than those under 60, but one prospective study found no relationship between patient age and incidence of such infections (26,196).

Sterile techniques for mixing the formula, setting up the infusion system, and maintaining the catheter are essential (26,57,111,155). Incidence of catheter-related infections has decreased in the past 15 years because of the use of sterile techniques (61). Nevertheless, these infections have been the primary reason for rehospitalization of patients on TPN at home in each year for which information is available (1979 to 1983) (149,150, 151,152,153).

Other potential complications of TPN are mechanical problems with insertion and maintenance of the catheter and metabolic problems related to the formula. Isolated cases of death due to air entering the veins via a TPN catheter have also been reported (134). For long-term TPN patients, micronutrient deficiencies are frequently a problem (155).

Table 8-2.—Standard TPN Formula (24 hours) for a 70-kg Adult

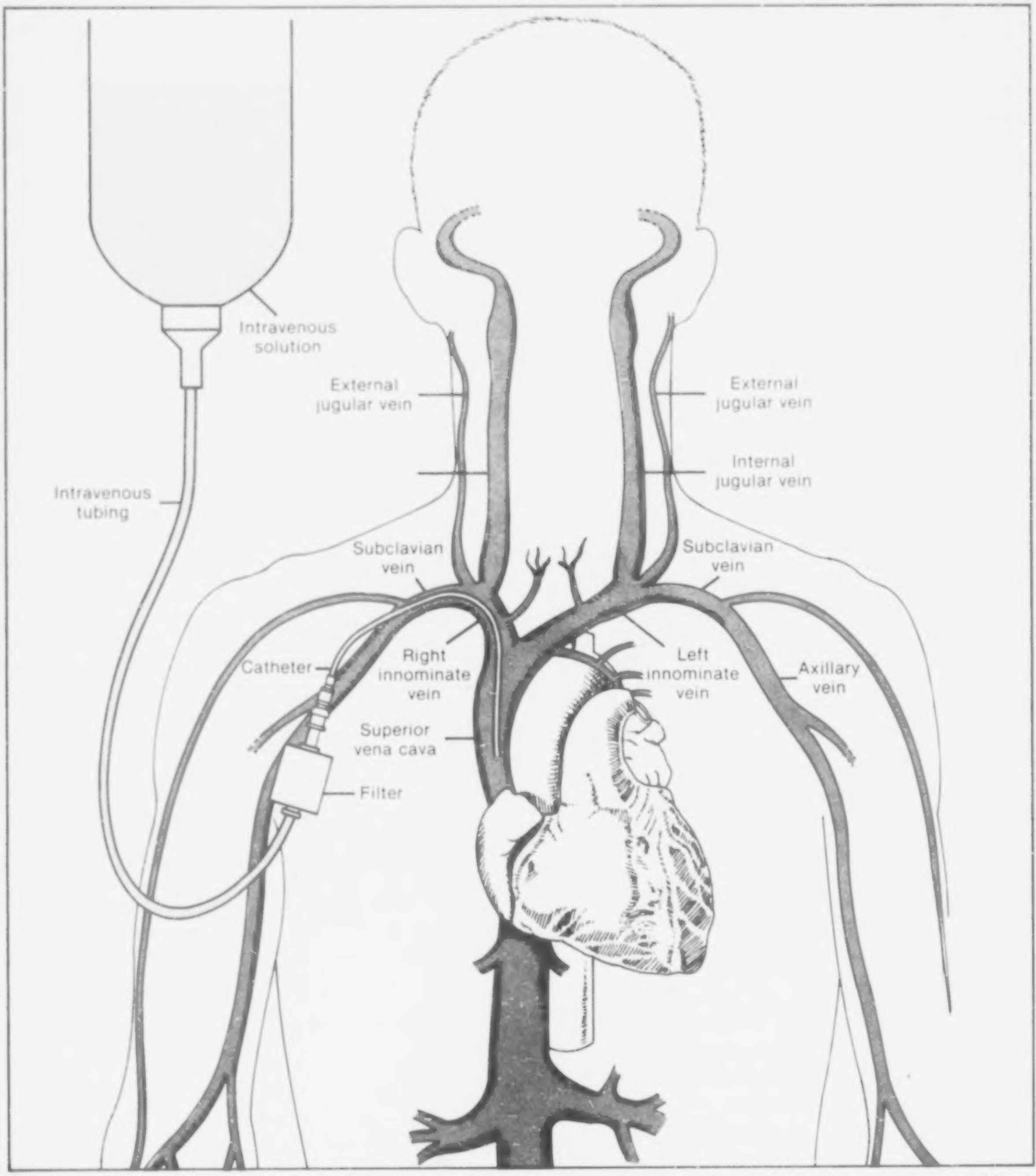
Fluid	3 liters
Protein (amino acids)	0.2 to 0.3 g nitrogen/kg
Calories[a]	25 to 40 kcal/kg
Essential fatty acids (lipids)	2% of total calories
Electrolytes:	
Sodium	100 mEq
Potassium	100 mEq
Chloride	130 mEq
Acetate/gluconate	90 mEq
Calcium	15 mEq
Magnesium	20 mEq
Phosphorus	300 mg
Trace Elements[b]:	
Zinc	5 mg
Copper	1.5 mg
Iodine	120 µg
Selenium	100 µg
Chromium	15 µg
Manganese	2 mg
Vitamins:	
Ascorbic acid	100 mg
Thiamine	3 mg
Riboflavin	3.6 mg
Niacin	40 mg
Pantothenic acid	15 mg
Pyridoxine	4 mg
Biotin	60 µg
Folic acid	400 µg
Cobalamin	5 µg
Vitamin A	4,000 I.U.
Vitamin D	400 I.U.
Vitamin E	15 mg
Vitamin K	200 µg

[a] Provided principally as dextrose.

[b] Iron may be added to the formula at 1 to 3 mg per day or given by mouth or intermuscularly.

SOURCE: Oley Foundation, "Nutritional Support and Hydration for Critically and Terminally Ill Elderly," prepared for the Office of Technology Assessment, U.S. Congress, Washington DC, November 1985.

Figure 8-2.—A Typical TPN Catheter Placement


Intravenous solution
External jugular vein
External jugular vein
Internal jugular vein
Intravenous tubing
Subclavian vein
Subclavian vein
Catheter
Right innominate vein
Left innominate vein
Axillary vein
Superior vena cava
Filter

Concentrated nutrient solution is infused through a catheter into the superior vena cava, the 1-inch vein that returns blood to the heart from the upper part of the body. The catheter is inserted into the right subclavian vein and pushed along until its tip is in the superior vena cava. The catheter can also be inserted through the left subclavian vein or one of the jugular veins (72).

SOURCE: S.J. Dudrick and J.E. Rhoads, "Total Intravenous Feeding," *Scientific American* 226(5):73-80, 1972.

In hospitals, metabolic complications including alterations in blood glucose and phosphorus are the most common complication of TPN (230). Although such complications can reflect errors in the TPN formula, they also occur as the patient's metabolism and nutrient requirements change in response to TPN. They can usually be anticipated and minimized with careful monitoring by professionals trained in the use of TPN (57,111,137).

The Patient's Experience of TPN

As it does with tube feeding, the patient's experience of TPN varies depending on his or her general physical and mental condition. Critically ill patients on short-term TPN may be no more bothered by intravenous feeding than by other treatments. Those who require long-term TPN, however, face significant physical and psychological obstacles to acceptance of the treatment. The catheter that remains in the chest can be both annoying and frightening. In addition, patients must cope with the feeling of dependency on the treatment, fears about life-threatening complications, and anxiety about the cost of treatment. Despite these problems, many patients on long-term TPN at home lead active and satisfying lives (155).

Photo credit: Oley Foundation

The TPN catheter that remains in the patient's chest can be both annoying and frightening, but many patients on long-term TPN adjust well to the treatment.

Anecdotal evidence indicates that TPN, unlike tube feeding, is seldom used for long-term treatment of confused patients. When it is used for confused patients who may try to pull out the catheter, physical restraints are necessary because pulling out, disconnecting, or tearing a central venous cathether is dangerous, although not usually life-threatening.

Tube Feeding v. TPN

Tube feeding is often perceived as inexpensive and relatively simple (44,132), whereas TPN is perceived as expensive, "high-tech" medical care that requires the involvement of skilled professionals. This dichotomy obscures important similarities between these procedures. In fact, both procedures are used for acute and long-term treatment, and while TPN is generally more complex and hazardous, tube feeding also entails risks and requires the involvement of skilled professionals, at least for clinically complex patients (90,125).

The primary determinant of which feeding method is used is the patient's physical condition. Nutritional support specialists agree that tube feeding should be used if the patient is capable of digesting and absorbing food and fluids normally; if not, TPN is required. In the vernacular of the field, "If the gut works, use it." Yet TPN is sometimes used when tube feeding is possible and might be more effective (90,126,170,175,210). This use of TPN may occur because of staff training and preferences or because third-party reimbursement may be easier to obtain for TPN than for tube feeding.

Clinical Research Issues Related to the Use of Nutritional Support and Hydration for Elderly Patients

Although tube and intravenous nutrition and hydration procedures are widely used, many clinical questions about the procedures, particularly their use for elderly patients, remain unanswered. Some of the most important questions are summarized below. Research on each of these questions is needed to improve clinical decisionmaking and quality of care for elderly patients.

Efficacy of Nutritional Support

Tube and intravenous nutritional support and hydration are clearly effective in sustaining life for patients of all ages who are physically unable to swallow, digest, or absorb food and fluids taken by mouth and for patients who do not take in food or fluids for whatever reason. Efficacy has been more difficult to demonstrate for critically ill patients who are physically able to eat but cannot eat enough to maintain normal nutritional status. Nutritional support improves the indices of nutritional status in these patients (116), but efficacy in terms of outcome measures such as mortality, morbidity, or length of hospital stay has been more difficult to demonstrate (14,60,79).

Some nutritional support specialists argue that "there are no illnesses that do better when the patient is starved" and that efficacy has been demonstrated as definitively for nutritional support as for most other medical treatments (91). Others believe that efficacy in terms of outcome measures has been established for some diseases but not others, for which it is, nevertheless, frequently used.

Among patients with the same disease, nutritional support may be essential for those who are more severely ill and unnecessary for those who are less severely ill (14). In this case, the difficulty of measuring severity of illness may complicate the process of establishing efficacy.

Clearly, there are some severely ill, malnourished patients who will die even with nutritional support. Predicting outcome is difficult, but one study of patients of all ages in an intensive care unit (48) used APACHE II, a clinical assessment instrument developed to classify severity of illness, to predict outcome in the patients who received TPN. The system predicted death with 100-percent specificity—that is, all eight TPN patients who were predicted to die in the hospital did die. (Seven other patients who were predicted to live also died in the hospital.) Withholding TPN from patients who were predicted to die and then did die would have reduced the annual cost of TPN to the hospital by 28 percent. The researchers conclude:

> The disparity between demand and available health care resources is a universal problem. Political and bureaucratic measures are increasingly being imposed on the medical profession to reduce health care costs. These measures are often viewed by the medical profession as being harmful to patient care and clinical freedom.
>
> One way to improve cost-effectiveness is to examine critically the way we prescribe expensive therapies . . . . By not treating patients who will not benefit, cost-effectiveness is increased, with a simultaneous reduction in the total cost. The ethical problem is to identify these patients accurately (48).

The American Society for Parenteral and Enteral Nutrition recently issued guidelines for use of TPN for hospitalized adult patients (12). These guidelines define conditions for which TPN should be a part of routine care, conditions for which it is usually helpful, conditions for which it is of limited value, and conditions for which it should not be used. The last category includes cases where the patient or legal guardian does not want TPN. No similar guidelines are available for tube feeding.

Several factors suggest that nutritional suppc might be less effective, on average, for older than younger patients. Physiological changes associated with normal aging might limit the capacity of a patient's body to respond to tube or intravenous feeding. In addition, the greater prevalence of acute and chronic conditions among elderly people might increase the risks of treatment for them. It should by noted, however, that these considerations apply to elderly people as a group, and, because of the heterogeneity of the elderly population, do not apply equally to all elderly persons. Moreover, since many elderly patients with acute and chronic diseases are malnourished, nutritional support might have a greater positive impact on outcome for elderly patients as a group than for younger patients.

Despite the relevance of these considerations to treatment decisions, OTA is aware of only one study (104) comparing efficacy for older versus younger patients. A comparison of responses to tube and intravenous feeding for 37 patients under age 65 and 65 patients over age 65 found no statistically significant differences between the groups in nutritional status indicators, although the direction of the findings indicated consistently poorer response among elderly patients. Mortality was significantly higher in the older group. More information about the efficacy of nutritional support for older patients is needed to support clinical decisionmaking.

Assessment of Nutritional Status in Elderly People

Determining an individual's need for nutritional support, selecting the appropriate feeding method and formula, monitoring the patient's response to treatment, and determining efficacy require a method for collecting information about a patient's nutritional status and standards with which to compare this information.

Various methods are used to assess nutritional status in individuals of all ages:

- *Dietary histories* that provide a record of calories, protein, fat, carbohydrates, vitamins, and minerals and sometimes alcohol and drugs consumed by the individual over a designated time period.
- *Anthropometric measurements* such as weight and measures of lean body mass and fat stores (e.g., skinfold thickness and arm circumference).
- *Biochemical measurements* such as levels of serum albumin and serum transferrin.
- *Hematologic measurements* that can be used to identify anemia related to lack of specific nutrients.
- *Measurement of immune responses* such as total lymphocyte count and cell-mediated immunity.
- *Measurement of vitamin and mineral status*.

Changes in body composition and metabolism associated with normal aging are known to affect the indices of nutritional status used in these assessment methods. Many of the effects are not fully understood, however, and nutritional standards that take these effects into account have not been developed. The lack of standards makes it difficult to interpret findings for individual elderly patients.

For example, dietary requirements for elderly people are unknown or controversial for many nutrients. On average, caloric needs are reduced in elderly people because of decreased physical activity and decreased metabolic rates associated with smaller lean body mass. It is unclear, however, whether protein requirements are generally increased or decreased in elderly people. Requirements for fats, carbohydrates, and many vitamins and minerals are also unknown. The need for some nutrients may be increased because of reduced absorption of these nutrients associated with normal aging (51,115,142,181).

Recommended Dietary Allowances (RDAs) formulated by the National Research Council are available for the age group 51 +. The use of a single set of RDAs for the age group 51+ fails to account for important physiological differences between people who are under age 60, for example, and people over age 80 or 90. A new edition of the RDAs was scheduled for release in 1985 but has been delayed, partly because of the difficulty of establishing RDAs for elderly people (141, 181).

Anthropometric measures such as fat stores and lean body mass are used to determine nutritional status in patients of all ages, but lack of standards for interpreting findings for elderly patients complicate their use for these patients. For example, skinfold thickness is used as a measure of fat stores, but alterations in fat distribution, skin elasticity, and other characteristics of aging skin make skinfold measurements difficult to interpret after age 60 (34,60,80). Similar problems limit the usefulness for older persons of each of the assessment methods listed above. These problems are discussed further in appendix F.

In addition to being affected by normal aging, nutritional status is affected by acute and chronic diseases, and accurate assessment of a patient's nutritional status requires an understanding of their effects. Many of the diseases that affect nutritional status—e.g., acute and chronic infections, cerebrovascular and cardiovascular disorders, cancer, and chronic renal, pulmonary, and liver diseases—occur in patients of all ages but are more common in elderly people than in younger people. Decreased food and fluid intake is extremely common in patients with many of these diseases. Yet the same diseases often increase nutritional requirements. Gastrointestinal absorptive capacity is also altered by many diseases (115). In addition, treatments that cause nausea or lessen appetite and diagnostic procedures that require the patient to be without food or water for short periods affect nutritional status.

Acute and chronic diseases affect some of the commonly used indices of nutritional status. Cancer, congestive heart failure, and kidney and liver disease, for example, decrease the level of serum albumin, a frequently used biochemical measure of nutritional status, but lower serum albumin levels do not necessarily indicate malnutrition in patients with these diseases. Conversely, dehydration increases the level of serum albumin, but higher serum albumin levels in dehydrated patients may not indicate normal nutritional status (51).

Drug-nutrient interactions are common in elderly patients and must also be considered in assessing nutritional status. Elderly persons with acute and chronic diseases often take large numbers of drugs, some of which interfere with metabolism and can cause specific nutritional deficiencies. Many drugs also cause nausea or a reduction in appetite that can decrease food and fluid intake. Mood altering drugs can cause changes in cognitive function that markedly affect food and fluid intake (115,128,172).

The complexity of the relationship between nutritional status, normal aging, acute and chronic disease, and drug-nutrient interactions suggests that a thorough assessment is needed before treatment is initiated. According to many nutritional support specialists, however, simple, inexpensive assessment procedures can be used to screen people at risk for nutritional deficiencies (56,90,166, 184,210). Loss of 10 percent of usual body weight in 6 months or less is one such screening measure (53). At one hospital, surgical patients who had lost 10 pounds or more in the preceding 6 months were more likely to die following surgery than those who had not experienced a weight loss of this magnitude. Among those age 60 and over, the death rate was 11 times higher for those who had lost 10 pounds or more than for those who had not (184).

Simple indicators like weight loss are useful for initial screening, but a thorough nutritional assessment is needed to select an appropriate formula or monitor response to treatment. For elderly people, research is needed to develop valid nutritional assessment procedures, including accurate nutritional standards for different age groups within the elderly population.

The Adequacy of Nutritional Formulas for Elderly People

Changes in body composition and metabolism associated with aging may necessitate adjustments in nutritional formulas for some or most elderly patients. Relevant age-related changes include decreased metabolic rate; decreased glucose tolerance; and changes in cardiac and kidney function that limit the patient's tolerance of the large volume of fluids required for TPN (51,55).

TPN formulas and modular enteral formulas are individually mixed and can be adjusted for elderly patients if the health care professionals treating these patients are aware of the necessary changes. To some nutritional support specialists, the necessary changes may be obvious. To health care professionals who are managing TPN and tube feeding for elderly patients but are not trained in clinical nutrition, however, the necessary changes may not be so clear.

Many, and perhaps most, elderly patients on tube feeding receive premixed formulas that are used exactly as they are received from the manufacturer. Lack of information about the dietary needs of elderly people—particularly very old people and those who are bedridden or otherwise extremely inactive—raises the possibility that some elderly patients on tube feeding receive formulas that are inappropriate for their needs.

Another clinical issue is the adequacy of nutritional formulas for long-term use by patients of all ages. Insufficient or excessive amounts of specific nutrients may not affect patients on short-term treatment but can have a significant effect over time. Even if the correct amounts of certain nutrients are known and included in the solution, tube and intravenous feeding procedures can prevent their absorption and utilization. Infusion of nutrients directly into a person's veins, for example, results in immediate excretion of some nutrients that are normally stored in the liver. Nighttime infusion of nutritional formulas also affects absorption and utilization. As a result, some long-term nutritional support patients develop obscure deficiency syndromes (77,155). Clinical research on formulas for long-term use is needed.

The Effects of Withholding and Withdrawing Nutritional Support and Hydration

Clinical observation suggests that terminally ill people often reduce their intake of food and water as death approaches. For patients who are only hours or a few days away from death, dehydration can lessen nausea, vomiting, abdominal pain, and pulmonary secretions that cause gagging and choking and decrease the patient's level of consciousness and thus his or her perception of pain (29,180,234). For this specific group of patients, withdrawal of nutritional support may improve the quality of the individual's last hours or days. Some of these patients may suffer from thrist or dry mouth when treatment is withdrawn, but these symptoms can usually be alleviated with frequent mouth care, ice chips, small amounts of water, vaseline, and a room humidifier.

Little is known about the effects of withdrawing nutritional support and hydration and the course of dying without treatment for people who are terminally ill, comatose, or severely debilitated but for whom death is not imminent (122). Yet some discussions about withdrawing treatment from these patients are based on what is known about withdrawing treatment from patients for whom death is imminent. Caregivers point out, however, that some comatose, severely debilitated, and even terminally ill patients live a long time after nutritional support has been withdrawn and that malnutrition increases their susceptibility to infections and can cause deep decubitus ulcers that are painful for the patient and demoralizing for caregivers (130,163). Furthermore, although it is assumed that comatose patients do not experience hunger and thirst, it is not known to what extent severely debilitated and terminally ill patients for whom death is not imminent experience these feelings. More information is needed about the physiological effects of withholding and withdrawal for such patients.

A related clinical question pertains to the use of intravenous fluids when nutritional support has been withdrawn. Many caregivers are more reluctant to withdraw intravenous fluids than to withdraw tube feeding or TPN (133,155,192). On the other hand, continuing intravenous fluids after withdrawing feeding may prolong a patient's dying. Some terminally ill cancer patients are tube fed modified formulas that are not intended to meet their caloric or protein needs, but only to keep them hydrated and presumably more comfortable (155). Clinical research on the effects of these partial treatments is needed.

Ethicists and clinicians emphasize that a decision to withhold tube or intravenous nutrition and hydration should not mean abandonment of the patient and that palliative care should always be provided (35,121,228). Some of the nursing care measures described above, such as the use of ice chips to alleviate thirst, may lessen suffering for some dying patients. Other patients may be able to eat or drink small amounts of food or fluids that are insufficient to maintain life but nevertheless physically and emotionally satisfying. Tube and intravenous feeding are impersonal treatments, and in some cases, the decision to stop them and offer food and fluids by mouth instead may be comforting for the patient. For some families, the opportunity to bring in special foods or help with hand feeding is comforting (35,106,121,228). Clinical evaluation of these treatment approaches is needed.

The Relationship Between Dementia and Eating Disorders

An unknown number of patients on long-term nutritional support, especially tube feeding, have neurological diseases that cause dementia, but little is known about the relationship between these diseases and eating disorders. Parkinson's disease and stroke are known to cause physical difficulty with swallowing (46), and some patients with these diseases have dementia. Alzheimer's disease—the most frequent cause of dementia in elderly people—can also cause swallowing difficulty, at least in some patients (215). However, little is known about the prevalence of swallowing difficulties in persons with Alzheimer's disease or how often such conditions necessitate tube feeding. It is not known why some people with Alzheimer's disease or other dementing disorders stop eating while others do not, why some refuse hand feeding, and whether or how often these behaviors are related to swallowing disorders.

One study (190) found that 32 percent of the residents of one nursing home could not eat without physical assistance of some kind. The need for assistance was not correlated with a diagnosis of dementia or stroke, but it was highly correlated with swallowing disorders. The need for assistance was also correlated with low scores on a measure of cognitive ability—the Mini-Mental State Exam (MMSE) (78). None of the nursing home residents with an MMSE score indicating normal cognitive ability required assistance with eating, but 25 percent of those with scores indicating moderate cognitive impairment and 75 percent of those with scores indicating severe cognitive impairment required such assistance. Seven (9 percent) of the residents at this nursing home were tube fed. Of these seven, the researchers were able to examine four, all of whom had severe cognitive impairment (189).

Although cognitive impairment was correlated in this study with need for assistance in eating, cognitive impairment did not predict the need for assistance independent of swallowing difficulties. The researchers suggest that swallowing difficulties may be associated with only a specific type of dementia or only particularly severe dementia. In this context, it is important to note that 25 percent of residents with severe cognitive impairment were able to eat independently (190).

Another study (226) indicates that swallowing difficulties may not be common among Alzheimer's disease patients, even in the late stages of the disease. Some research suggests that eating disorders among these patients tend to develop when the patients have an infection, such as bronchial pneumonia, that decreases appetite (179,225).

Some people may believe that persons with dementia who do not eat should be tube fed regardless of the reason they do not eat; others may conclude that such persons should not be tube fed, again regardless of the reason they do not eat. A third group of people, however, may consider the reason for a dementia patient's eating problem a relevant factor in treatment decisions, and conclude, for example, that the decision to tube feed a dementia patient who has swallowing difficulty is less problematic than the decision to tube feed a dementia patient who does not eat for other reasons. In any case, good medical care requires greater understanding than now exists about the relationship between dementia and eating disorders.

Another problem in decisions about nutritional support for dementia patients is lack of information about the course of diseases that cause dementia (215) that makes it difficult to determine when such patients are terminally ill and how long they may live with and without treatment. Claire Conroy, a severely confused elderly woman who was the subject of intense legal debate about withdrawal of tube feeding, for example, died during early court proceedings even though it had not been expected that she would die imminently and tube feeding had not been withdrawn. If it had been clear that she was terminally ill and would die imminently with or without treatment, it is unlikely that her case would have been so controversial.

Federal Funding for Research on Nutritional Support for Elderly People

Federal funding for research on nutritional support is provided primarily by the National Institutes of Health, but none of the projects currently funded by the National Institutes of Health focus on use of these procedures for elderly people (193). The National Institute on Aging and the Department of Agriculture are funding research on nutrition and normal aging and the dietary requirements of healthy elderly people (81). The VA is funding several studies on nutritional support, most of which are not focused on elderly patients. However, the VA Geriatric Research, Education, and Clinical Center at Little Rock, Arkansas, conducts an ongoing research program on nutritional support for elderly patients. The VA Geriatric Research, Education, and Clinical Center at Bedford, Massachusetts, is conducting research on eating disorders in persons with dementia.

Some of the research that is needed to improve clinical decisionmaking and the quality of nutritional support procedures for elderly persons is basic biomedical research on human nutrition, nutrition and normal aging, and the relationship between nutrition and disease. Applied research to identify, develop, and evaluate products that meet the nutritional needs of elderly people is also needed. Some of the most important research questions, however—questions about the impact on patient comfort of withholding or withdrawing nutritional support and hydration from severely debilitated, comatose, and terminally ill persons who are not expected to die imminently; about the relationship between dementia and eating disorders; about reasons for patient refusal of tube or intravenous feeding; and about palliative care for persons who refuse the procedures or for whom they are futile—are primarily nursing issues. They may be best defined and addressed through the newly established National Center for Nursing Research at the National Institutes of Health. Other important questions, particularly questions about efficacy and patient comfort associated with different nutritional support procedures, are best addressed by nutritional support specialists, who are familiar with the range of treatment options and their pros and cons for different types of patients.

Professional Training and Expertise in Nutritional Support

Given the gaps in knowledge cited above, appropriate treatment decisions and ongoing care for elderly patients require the involvement of personnel who are trained to recognize malnutrition and eating disorders, to interpret assessment findings, to provide tube and intravenous nutrition and hydration, and to monitor patient response to treatment. Although some health care professionals who treat critically and terminally ill and severely debilitated elderly people have the requisite training in these areas, many do not.

In general, physicians and dietitians are responsible for nutritional assessment and treatment, although in many settings, nurses may be the first to notice eating disorders and symptoms of malnutrition and are often the direct caregivers. Pharmacists are responsible for preparing TPN and, in some cases, enteral formulas (see ch. 10).

Physician training in basic human nutrition has been very limited (66,74,119,147,233). A recent survey by the National Research Council's Food and Nutrition Board found that only 27 percent of medical schools in the United States have required courses in nutrition. The National Research Council's report, *Nutrition Education in U.S. Medical Schools*, notes in particular the lack of medical training in enteral and parenteral nutrition and nutritional aspects of chronic disease, and it points out that medical board examinations now include no questions on enteral or parenteral nutrition or nutrition and the elderly (145).

All dietitians are trained in basic human nutrition and procedures for nutritional assessment. Dietitians also receive training in nutritional care of elderly people, but there is disagreement about the adequacy of this training. Most dietitians do not receive extensive training in assessment of critically ill patients. Dietetic training has changed with advances in nutritional support technology, so that dietitians trained recently are more familiar with current TPN and tube feeding techniques (49,194).

Pharmacists receive some training in nutrition throughout the pharmacy curriculum, although separate required courses on nutrition in the basic pharmacy program are unusual. The primary focus of their training in nutrition is the effects of malnutrition on drug therapy. Pharmacy students are usually introduced to parenteral and enteral nutrition in courses related to the selection and mixing of nutrient solutions (83,222).

Nurses receive training in basic nutrition and the importance of food and fluid intake in acute and chronic diseases. This training is often interspersed through the nursing curriculum, but a 1983 survey of nursing schools found that about half had separate required courses on nutrition (83). Yet many nurses have little training in nutritional support procedures, especially TPN.

Despite these generalizations about lack of training in clinical nutrition, some physicians, dietitians, pharmacists, and nurses have gained expertise in this field, partly through formal training but more often through experience in providing TPN and tube feeding, particularly in critical care settings. These nutritional support specialists work primarily in hospitals and are often members of nutritional support teams. Some have specific credentials in nutritional support, but many do not. There is currently no agreement about what credentials are needed and which organization or organizations should be responsible for certifying nutritional support specialists (195).[4] (See also ch. 10).

Some patients in hospitals and at home receive care from hospital-based nutritional support teams. Such teams, that usually include a physician, a nurse, a dietitian, and a pharmacist, assist hospital staff with assessment and nutritional support of patients. In addition, some patients in hospitals, nursing homes, and at home, receive nutritional support services from individual professionals who have the necessary training and experience in clinical nutrition. However, as discussed in the following sections of this chapter, patients in some settings do not have the benefit of staff trained in nutritional assessment, tube feeding, or TPN. As a result, some elderly patients who might benefit from nutritional support may not be identified, and others may receive inappropriate treatment.

It has been noted that treatment options for elderly people are often limited by lack of knowledge about their special needs, a shortage of trained health care professionals to treat them, and other factors. As a result, the "best choice" for treatment is frequently not available (27). This observation accurately describes the current status of nutritional support and hydration for elderly patients in many treatment settings. Development of nutritional standards for elderly people, simple screening measures, and increased training for physicians, dietitians, pharmacists, and nurses in enteral and parenteral procedures and special considerations in their use with elderly patients could help to alleviate this problem.

UTILIZATION AND COST OF NUTRITIONAL SUPPORT AND HYDRATION

Industry data indicate that in 1984 about 1.4 million patients of all ages received nutritional support, 96 percent of them in hospitals (7) (see table 8-3). Although nutritional support techniques are basically the same in different settings, there are significant differences across settings in patient characteristics, health care personnel, cost of care, and reimbursement. Therefore, each setting is discussed separately.

Utilization and Cost of Nutritional Support and Hydration in Hospitals

Utilization of Nutritional Support in Hospitals

Industry sources estimate that more than 500,000 individuals of all ages received TPN in hospitals in 1984 and about 780,000 received tube feeding (7). Precise figures are not available because nei-

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[4] The American Society for Parenteral and Enteral Nutrition has published standards of practice for nutritional support nurses (10) and nutritional support dietitians (11), and standards have been drafted for pharmacists involved in the care of patients on nutritional support (13).

Table 8-3.—Persons Receiving Nutritional Support by Location and Type of Therapy, All Ages, 1984[a]

Location	Parenteral feeding		Enteral feeding		Total	
Hospital	536,200	(96%)	780,300	(92%)	1,316,500	(94%)
Nursing home	15,600	(3%)	53,400	(6%)	69,000	(5%)
At home	4,600	(1%)	14,400	(2%)	19,000	(1%)
Total	556,400	(100%)	848,100	(100%)	1,404,500	(100%)

[a] These figures are from a marketing survey by Charles H. Kline Co., Fairfield, NJ. They provide valuable information about utilization but are considered high by some nutritional support specialists (68).

SOURCE: American Society of Parenteral and Enteral Nutrition, "1984 Nutritional Support Population Exceeds 6 Million," *Update* 8(4):8, 1985.

ther hospitals nor third-party payers regularly collect this information. Until late 1986, the widely used ICD-9 coding system had no procedure codes for tube feeding or TPN. Thus, there was a serious obstacle to collecting information on the utilization of these procedures. Newly assigned procedure codes for these procedures will facilitate data collection in the future.

Although no national figures are available on the number of elderly people who receive nutritional support in hospitals, reports from individual hospitals indicate that approximately 40 percent of the patients receiving TPN and 50 percent of those receiving tube feeding in hospitals are over age 65 (115). However, the percentages vary greatly in different hospitals.

Little is known about the characteristics of elderly patients on nutritional support in hospitals, but one 1984 study at the Albany Medical Center Hospital compared elderly patients who received nutritional support to those who did not. Of the 96 randomly selected subjects, 25 percent received tube feeding or TPN: 71 percent of these received only tube feeding; 12 percent received TPN, and 17 percent received both. There was a trend, although it was not significant, toward decreasing utilization with age—31 percent of patients aged 65 to 69 received nutritional support compared to only 21 percent of those over 70 (155).

About half of the elderly patients who received nutritional support in this study had diagnoses indicating central nervous system damage (notably stroke) compared to only 6 percent of those who did not receive nutritional support. About 20 percent of patients in each group had cancers of various types; in the group that received nutritional support, all the cancer patients had local or metastatic bowel involvement (155).

Comparison of the two groups of elderly patients on the basis of a functional assessment rating scale showed that the patients receiving nutritional support were more impaired in physical and mental health, activities of daily living, and ability to care for themselves independently. Their average length of hospital stay was significantly longer; a larger percentage died in the hospital; and a smaller percentage were discharged home compared to the patients who did not receive nutritional support (155). Although these findings cannot be generalized beyond the population surveyed, they do agree with findings of other studies showing that nutritional support patients of all ages are generally sicker and more functionally impaired than other patients with similar diagnoses (14).

Nutritional support, particularly TPN, is used for patients with each of the life-threatening conditions discussed in other chapters of this report—i.e., cardiac, respiratory and renal failure, and severe infections. Ventilator-dependent patients exemplify the complex relationship between nutritional support and other life-sustaining treatments. Patients who have an endotracheal tube (a tube placed through the mouth or nose into the trachea) for mechanical ventilation cannot take in food or fluids by mouth and, therefore, require tube feeding or TPN. Some patients on mechanical ventilation are also malnourished. Since malnutrition is associated with reduced ventilatory drive and ventilatory efficiency, nutritional support could be expected to improve outcome for these patients. Nutritional support may also be beneficial in weaning patients off mechanical ventilators (24,110). However, high glucose loads increase respiratory distress in some patients. Thus, the selection of an appropriate formula for a ventilator-dependent patient requires knowledge of the interaction of nutritional status, specific nutrients, and respiratory function. Moreover, frequent monitoring of the patient's response to nutritional support is essential to avoid complications and insure optimal outcome (20,73,86,143).

Malnutrition is common among hospital patients. The prevalence of malnutrition ranges from 17 to 60 percent among hospital patients of all ages (28,31,32,108,208) and is higher among elderly hospital patients than younger ones (28,91). Malnutrition is associated with increased morbidity, mortality, length of stay, and cost of care. One recent study of 800 hospitalized patients of all ages found that 55 percent were malnourished (4). Malnourished patients were three times more likely to die or suffer major complications than patients with normal nutritional status. Among patients who had pneumonia, hip fractures, or inflammatory bowel disease, those who were malnourished stayed an average of 2 days longer in the hospital, cost the hospital $1,160 more, and had charges of $2,480 more than those with normal nutritional status. Among patients undergoing hip, bowel, or abdominal vascular surgery, those who were malnourished spent 5 days more in the hospital, cost the hospital $2,750 more, and had charges of $5,575 more than those with normal nutritional status. Cost of care was higher, on average, for elderly patients but was much more closely correlated with the patients' nutritional status than their age (91).

Many malnourished patients can be treated with oral nutritional supplements and do not need tube feeding or TPN. Among the very large number of hospitalized elderly patients who are malnourished, however, some need tube feeding or TPN and do not receive it—sometimes because their poor nutritional status has not been identified or because its potential effect on clinical outcome is not recognized (137). No estimate of the number of these patients can be derived from available data, however.

Nutritional Support Personnel in Hospitals

Some hospitals have nutritional support teams to assist with or provide treatment, as discussed above. All VA medical centers that provide TPN are required to have a nutritional support team (114). But a 1984 survey of other hospitals found that only about 12 percent have a nutritional support team or a nutritional support service group (204).

Research indicates that clinical procedures necessary for safety and efficacy are frequently not followed and complications are more frequent when a nutritional support team is not involved in treating hospitalized patients on tube or intravenous feeding (67,69,146,161,174). Although no supporting data are available, it may also be true that in hospitals that do not have a nutritional support team or nutritional support service group, malnutrition is not recognized as frequently as in hospitals that do have such a team or group.

Cost and Reimbursement for Nutritional Support in Hospitals

Accurate data on costs, charges, and expenditures for nutritional support are difficult to obtain. Available figures vary greatly from one hospital to another, and figures reported as "costs" are often actually charges (211). According to one survey, the average cost of formulas, equipment, and associated staff time for TPN for hospitalized patients in 1985 was $196 per day (range: $25 to $500) (115). Other studies report average costs ranging from $75 to $400 a day for TPN formulas and associated staff time for hospitalized patients (14). If a patient remains in a hospital specifically to receive nutritional support, then the cost of hospitalization should be added to these costs to determine the overall cost of care.

Tube feeding is less expensive. One study showed that the average cost of formulas, equipment, and associated staff time for tube feeding for hospitalized patients in 1985 was $43 a day (range: $4 to $132) (115). Other studies report averages of $18 to $32 a day (14).

Medicare, Medicaid, Blue Cross, and other third-party payers reimburse hospitals for the care of elderly patients on nutritional support. Table 8-4 gives estimates of the percentage of patients receiving payment from each source.

Medicare is the primary payer for hospitalized elderly patients, and some nutritional support specialists and others believe that Medicare's prospective payment system (PPS) based on diagnosis-related groups (DRGs) discourages the use of nutritional support for the following reasons:

- The fixed Medicare payment rates for patients in each DRG are based on the average cost of treatment in the past. Some observers ar-

Table 8-4.—Source of Payment for Parenteral and Enteral Nutrition, All Ages, All Settings, United States, 1984[a]

Source of payment	Parenteral nutrition	Enteral nutrition[b]
Medicare	33%	30%
Medicaid	8%	5%
Private insurance	58%	55%
Self pay	1%	10%

[a] Treatments provided in hospitals, nursing homes, hospices, and at home are included

[b] These figures include payment for oral nutritional supplements in addition to tube and intravenous feeding

SOURCE: "Nutrition Support," *Biomedical Business International* 8(3):23, 1985.

gue that utilization of nutritional support has increased in many DRGs and that current DRG payment levels do not reflect this increased utilization (1,113,178).

- Patients with very different levels of severity of illness are grouped in the same DRG, and DRG payment levels appropriate for the average patient in each diagnostic category are significantly lower than the cost of treating the most severely ill patients in that category. Patients who receive nutritional support may be in any one of a large number of DRGs, but they tend to be among the most severely ill patients in each category. Some observers believe that low levels of reimbursement relative to costs for these "DRG losers" may discourage some hospitals from admitting them (14,102,173) and discourage other hospitals from providing expensive nutritional support (144). Although it can be argued in response that low reimbursement relative to cost for severely ill patients is balanced by relatively high reimbursement for less severely ill patients in the same DRG, that observation may not hold in the case of hospitals that provide nutritional support more frequently in each DRG than other hospitals; such hospitals may not be adequately reimbursed under the present Medicare payment system.
- Some DRGs cover patients with identical diagnoses except that one DRG includes patients who are over age 70 *or* have a comorbidity or complicating condition,[5] while the companion DRG includes patients who are under age 70 *and* have no comorbidity or complication. Medicare payment is higher for the former DRG than for the latter. Malnutrition qualifies as a comorbidity or complication for some DRGs, and malnourished patients are included in the higher reimbursement category. However, in the case of patients who are over age 70—and are in the higher reimbursement category by virtue of their age—malnutrition does not increase the reimbursement the hospital receives for their care.
- Many patients who need nutritional support are classified as *outliers* under DRGs, usually because of length of stay significantly greater than average. Some people believe that the Medicare payment for outliers is insufficient to cover a hospital's costs in caring for these patients (14,102).

At congressional hearings prior to formation of the Prospective Payment Commission (ProPAC), the body established by Congress to recommend to the Department of Health and Human Services adjustments in PPS to accommodate new technologies and changes in utilization patterns, nutritional support was specifically cited as an example of medical treatments that would require study (8). In 1985, at the urging of the nutritional support industry and professional groups, ProPAC approved a study of Medicare payment for TPN (168). The study was canceled in 1986, however, primarily because lack of procedure codes for TPN made it impossible to collect the necessary data. It may be reinstituted in the future if ProPAC continues to receive complaints about Medicare reimbursement for TPN (209).

One finding that would encourage the use of nutritional support, especially in the context of PPS, is proof that it saves hospital costs—i.e., that nutritional support decreases complications and length of stay, and, therefore, overall costs of hospital care (14,112,164,178,211). Proving this has been difficult, partly because of problems in defining severity of illness and identifying two groups of malnourished patients with comparable severity of illness, one of which was provided with nutritional support and the other not. A VA study (41) designed to overcome many of these problems is in progress, but the VA study addresses only surgical patients, and research on other patient groups is needed.

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[5] See ch. 2 for a discussion of comorbidity and complications.

Medicaid coverage of nutritional support in hospitals varies by State, but in general, Medicaid pays for hospitalization and inpatient nutritional support for elderly people with low income and no Medicare coverage. In some States, however, the number of days of care that is covered and the level of reimbursement are very low. Blue Cross and other commercial insurers also pay for nutritional support in hospitals (8).

The VA provides treatment without charge for veterans in VA hospitals. OTA has not reviewed VA coverage or payment policies for nutritional support and hydration.

Medicare Part B (Supplementary Medical Insurance) reimburses physicians for hospital visits for nutritional support of their patients, and some analysts believe that higher payments to physicians for TPN than for tube feeding may encourage inappropriate use of TPN.

No national regulations limit the frequency of physician visits for nutritional support (84). However, Part B reimbursement is handled by 50 carriers across the country, each of which has considerable discretion in coverage policy (214). Some carriers, for example, the Illinois carrier, have issued guidelines for payment. For some time, the Illinois carrier limited coverage of physician visits related to TPN to once a day for the first 2 weeks, every other day for 2 weeks, and once a week thereafter; physician visits for tube feeding were limited to an initial visit and one followup visit (103). Medicare claims for visits in excess of these guidelines required special justification and were often denied.

Nurses, dietitians, and pharmacists who provide nutritional support services in hospitals are generally on salary, and their salaries were theoretically included in the cost figures used to establish Medicare's DRG payment levels. Unlike physicians, these providers do not receive any direct Medicare reimbursement. Nor is direct Medicare reimbursement provided for the services of a hospital's nutrition support team or a physician's services as administrator of such a team. In the context of cost-containment pressures created by PPS, a hospital must justify the salaries of these nutrition support professionals in terms of: 1) its commitment to high-quality care; 2) reduced malpractice liability; and/or 3) cost-effectiveness. It is not known whether the number of hospitals with nutritional support teams has increased or decreased in response to PPS.

Public Policy Issues for Nutritional Support in Hospitals

The primary public policy concerns emerging from the preceding discussion of the utilization of nutritional support in hospitals are the lack of skilled nutritional support professionals in some hospitals and the possible disincentives for the use of these procedures arising from PPS. These problems affect both access to treatment and quality of care for elderly patients in hospitals.

Utilization and Cost of Nutritional Support and Hydration in Nursing Homes

Utilization of Nutritional Support in Nursing Homes

Nutritional support and hydration are used more frequently in nursing homes than the other life-sustaining technologies discussed in this report, with the exception of antibiotics. Still, they are used for only a small percentage of all nursing home residents. Data from the 1985 National Nursing Home Survey show that about 26,000 nursing home residents (2 percent of all residents) were tube fed (220). Industry estimates for 1984 were slightly higher: Charles H. Kline Co. estimated that 53,400 nursing home residents (about 4 percent of all residents) received tube feeding and 15,600 residents (about 1 percent of all residents) received TPN (7).

Since about 85 percent of all nursing home residents are over 65 (218), it is apparent that most of those receiving nutritional support in nursing homes are elderly. Little else is known about their characteristics, diagnoses, functional or mental status, or average length of stay.

A 1984 survey of nursing homes[6] by the American Health Care Association found that an average of four residents per facility were receiving tube feeding and about one resident for each six facilities was receiving TPN. More than half the facilities responding to the survey reported that they did not admit patients who require TPN. One-sixth reported that in the preceding 6 months, they had transferred or denied admission to patients who required tube feeding or TPN because the patients' needs exceeded the facility's ability to provide services. Some commented that they lacked adequate staff to provide nutritional support. Others cited payment problems (5).

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[6] In 1984, the American Health Care Association, an organization representing 8,500 nursing homes and other long-term care facilities, surveyed its members about the use of nutritional support in their facilities. The response rate was low (5 percent), so results cannot be generalized, but the survey findings provide descriptive information about use of these treatments in some facilities.

State Medicaid regulations for licensing and certification of nursing homes affect utilization of nutritional support. In some States, Medicaid regulations mandate that certain nutritional support procedures cannot be used in nursing homes or in some types of nursing homes. In Washington, DC, intermediate care facilities (ICFs) can provide gastrostomy but not nasogastric or intravenous feeding (122).

Malnutrition among nursing home residents is common. One study (186) showed that many of the 115 residents of an Ohio nursing home (mean age 80) suffered from moderate to severe malnutrition by currently accepted nutritional standards (e.g., 43 percent had abnormally low weight/height measures). A similar study in 2 Illinois nursing homes (162) found that 57 percent of the 227 residents (mean age 73) were malnourished.

Most malnourished nursing home residents do not need tube feeding or TPN. Increased staff attention to nutritional status, improvements in the quality and presentation of meals, hand feeding, and oral nutritional supplements could correct their nutritional deficits in most cases. With such improvements, some nursing home residents who now receive tube feeding might be able to take in food and fluids by mouth. However, the number of such persons cannot be estimated because so little is known about why nursing home residents receive tube feeding or TPN.

Patients in a persistent noncognitive state—sometimes referred to as irreversible coma or persistent vegetative state—require tube feeding or TPN to survive. Despite the intense legal and ethical debate about the use of life-sustaining treatments for these patients, there is no reliable information about how many such patients there are in this country. Estimates of 5,000 to 10,000 are widely cited but cannot be confirmed. Data from the 1985 National Nursing Home Survey show that only about 1400 nursing home residents have a diagnosis of coma in their medical record (220), but individuals who are comatose are frequently given diagnoses that reflect the cause of the coma rather than a diagnosis of coma per se. No data are available on the number of persons in persistent noncognitive state (coma) in hospitals.

Nutritional Support Personnel in Nursing Homes

Lack of adequately trained staff to provide tube feeding and TPN is generally a more severe problem in nursing homes than in hospitals. Very few nursing homes employ nutritional support specialists. Thus, the responsibility for assessment, selecting formulas, and monitoring the resident's response to treatment lies with the physician, the facility dietitian, and nurses.

Physician visits are much less frequent to nursing home residents than to hospital patients (105), so physicians may be less involved in nutritional assessment and ongoing nutritional support for nursing home residents than for hospital patients. Dietitians are usually responsible for nutritional assessment in nursing homes, but Medicare and Medicaid regulations do not require a full-time dietitian, and many nursing homes get by with a dietary consultant who may be in the facility half time, 1 day a week, 1 day a month, or even less. The nursing home dietitian or dietary consultant may be responsible for nutritional assessment of 100 to 300 or more residents and also has other duties, such as recommending special diets, responding to resident complaints about the food, and in some facilities supervising the kitchen. If a dietitian is not available to assess each resident, that responsibility falls to nurses who are usually also responsible for day-to-day treatment (107,177).

Reliable information about how nutritional formulas are selected for nursing home residents is not available, but anecdotal evidence suggests that many nursing homes use premixed enteral formulas that are not adjusted to the needs of the individual. Concerns about the safety, quality, and suitability of enteral formulas, discussed earlier, may be particularly relevant for nursing home use, because many nursing homes run within very tight financial constraints. Thus, they may purchase the lowest cost formula with little awareness of possible concerns about quality. Prevailing practices in nursing homes for monitoring residents' physical response to nutritional support are not known, but it is likely that there are also problems in this area.

In 1985, a Texas nursing home corporation was charged with murder for the death of a tube fed resident whose formula contained only 636 calories a day (154). It is unclear whether this case reflects knowing or unintentional neglect. However, some observers believe that slow, unintentional starvation of tube fed residents may not be unusual in nursing homes because of lack of staff trained to assess nutritional status, select an appropriate formula, and monitor the patient's response to treatment (103).

Although lack of adequately trained staff is an obstacle to safe and effective use of nutritional support in many nursing homes, three recent developments may lead to improvements. First, nutritional support specialists, who have demonstrated little interest in elderly nursing home residents in the past, are now focusing more attention on clinical issues related to their care. Second, the American Health Care Association is developing educational materials for its member facilities on ethical issues in nutritional support, clinical procedures, and alternate treatment methods (5). Finally, in response to Medicare's prospective payment system, some nursing homes are upgrading their staffs to provide more skilled care, and some hospitals are developing alternate level of care units for patients who are not acutely ill but need care that cannot be safely provided in nursing homes (337,83,169).

Cost and Reimbursement for Nutritional Support in Nursing Homes

OTA was unable to obtain estimates of the cost of tube feeding or TPN in nursing homes. It is likely that costs vary greatly in different facilities due to differences in personnel, nutritional support procedures, and patient characteristics. It is also likely that charges for nutritional support in nursing homes are related to Medicare and Medicaid payment policies, as discussed below.

Some people believe that an important aspect of the cost of nutritional support is the cost of long-term nursing home care for comatose and severely debilitated patients who would have died without tube or intravenous feeding and hydration. Other people consider even the mention of such costs as objectionable.

No information is available about the cost of nursing home care for patients on nutritional support. The average cost of nursing home care varies greatly among States and in different facilities, but generally costs $20,000 to $30,000 or more per year (219).

Medicare covers nutritional support for nursing home residents under the Part B prosthetic device benefit that reimburses 80 percent of allowable charges. The resident, resident's family, Medicaid, or other third-party insurance is responsible for the remaining 20 percent.

Medicare Part B reimbursement for enteral nutrition in nursing homes is very controversial. Before 1980, nursing homes generally purchased enteral supplies in bulk and included the cost of the supplies in their daily charges for care. Beginning in 1980, medical supply firms developed a new marketing approach: enteral supplies were provided at no cost to the nursing home and billed to Medicare separately for each resident, usually at the same rate as supplies for patients on enteral nutrition at home. In 1984, the Inspector General recommended that Part B coverage of enteral supplies be eliminated for nursing home residents because charges for these supplies were excessive (two to three times open market prices). The Inspector General also recommended that nursing homes be allowed to include the cost of enteral supplies in their daily charges for patients whose nursing home care is covered by Medicare —a very small proportion of all residents. This approach was rejected because it would eliminate Medicare coverage of enteral supplies for the large proportion of residents whose nursing home care is not covered by Medicare (221). Instead, proposals by the Health Care Financing Administration (HCFA) would limit the amount of reimbursement for enteral supplies. The effect of this limitation on access to nutritional support for nursing home residents is not known.

One point of disagreement between HCFA and medical supply firms is whether the firms that provide enteral supplies to nursing homes also provide other reimbursable services. The firms argue that they often provide training for nurses and other services for residents on tube feeding. HCFA claims that the firms seldom supply services for residents and that if training for nurses is needed, the nursing home should pay for it.

Medicaid policies that affect payment for nutritional support for nursing home residents vary considerably among States. Some States reimburse nursing homes at a flat rate for each Medicaid resident and make no additional payment for tube or intravenous feeding. Other States pay extra for residents who require tube or intravenous nutrition and hydration. This additional payment is included in the daily rate in some States, while in others Medicaid reimburses the nursing home separately for supplies and equipment used for each Medicaid patient. In many States, Medicaid reimbursement for tube or intravenous feeding requires prior authorization from the State Medicaid office (8). OTA has not analyzed the impact of differences among States in Medicaid coverage and reimbursement on the availability of these treatments.

The VA pays for long-term care of eligible veterans in community nursing homes and in VA hospitals, nursing homes, and domiciliary care facilities. No information was obtained by OTA about VA reimbursement for nutritional support and hydration for elderly VA patients in community nursing homes. Nutritional support for patients in VA facilities is provided without charge to the patient.

Medicare and Medicaid cover physician visits to nursing home residents, but the number of reimbursable physician visits is limited by both programs. As a result, frequent visits by a nutrition support physician, if one were available and willing to visit a nursing home resident, might not be reimbursed. Visits by dietitians or other nonphysician health care personnel are not reimbursed by Medicare or Medicaid, except insofar as they are included in the facility's daily charges.

Public Policy Issues for Nutritional Support in Nursing Homes

The most important public policy concerns emerging from the preceding discussion are the lack of information about the use of nutritional support procedures in nursing homes and questions about the quality of nutritional support procedures available to nursing home residents due to the lack of staff trained in nutritional assessment and nutritional support procedures. Particularly notable is the lack of involvement of skilled nutritional support specialists in the care of nursing home residents. Since Medicaid pays for almost half of the nursing home care in this country, improvements in quality of care for nursing home residents depend at least in part on Federal and State policies that determine level of reimbursement for Medicaid patients and required staffing in the facilities that care for them. Regulatory and reimbursement policies that encourage the involvement of nutritional support specialists in the treatment of nursing home residents could improve quality of care.

Utilization and Cost of Nutritional Support and Hydration in the Patient's Home

Utilization of Nutritional Support in the Home

Fewer patients of all ages receive tube feeding or TPN at home than in hospitals or nursing homes. Estimates range from 2,000 to 5,000 people of all ages on TPN and 15,000 to 20,000 on tube feeding (7,155).

The number of elderly patients on nutritional support at home is not known, but data from several sources[7] suggest that about 55 percent (range 17 to 59 percent) of people on tube feeding at home are over 65. This would be 8,000 to 11,000 elderly people. About 20 percent (range 15 to 29 percent) of people on TPN at home are over 65. This would be 300 to 1,500 elderly people (155).

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[7] These sources include three commercial home nutrition services representing about 5,400 patients and three relatively small registries representing about 1,400 patients. These sources overlap; that is, individual patients may be included in figures from two or more sources (155).

Data from one registry show that the percentage of elderly patients among patients receiving TPN at home increased from 5 percent in 1978 to 17 percent in 1983 (153). There are no data on the percentage of elderly patients among patients on tube feeding at home in earlier years, but the percentage has probably been increasing (155).

Cancer is the most common diagnosis of patients of all ages on TPN at home, but the proportion of patients with cancer varies from 10 to 48 percent depending on the reporting source. Gastrointestinal diseases and disorders, e.g., Crohn's disease, ischemic bowel disease, and motility disorders, are also common diagnoses of home TPN patients.

Diagnoses of people of all ages on tube feeding at home include cancer, neurological disorders, such as stroke, and nonmalignant metabolic disorders. Little specific information is available about the diagnoses of elderly patients on nutritional support at home, but some data suggest that there are fewer cancer patients among elderly than younger patients (155).

The general health status, functional ability, and quality of life of people on home nutritional support varies greatly depending on the underlying condition that necessitates nutritional support. People with nonmalignant gastrointestinal disorders can often live quite normally once they learn the treatment procedures. Although many of them would die without nutritional support, their condition is seldom life-threatening so long as treatment continues. Since nutritional support usually does not cure their underlying disease, however, these people are often permanently technology-dependent.

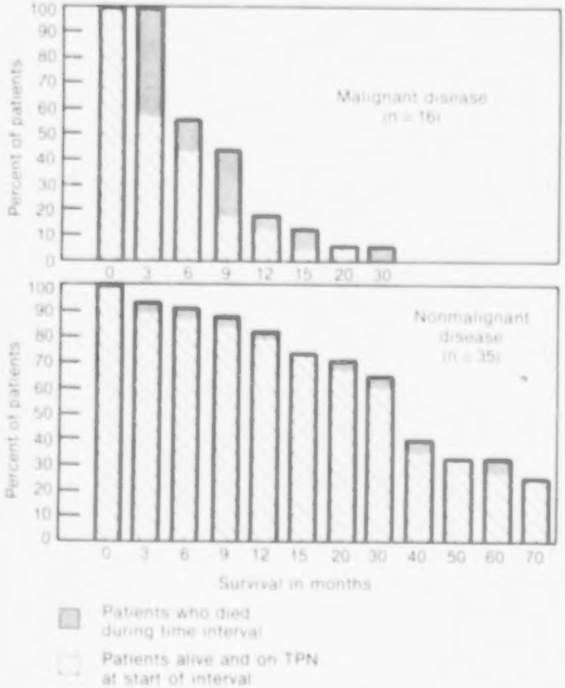
Nutritional support patients with cancer are often terminally ill and will die with or without tube feeding or TPN. In many cases, these procedures are used primarily to improve patient comfort, although in some cases, nutritional support can help to maintain their strength and may prolong their lives somewhat.

People with neurological disorders such as stroke may require nutritional support as a result of swallowing difficulty. For these patients, tube rather than intravenous techniques are usually used, and nutritional support can often prolong their lives significantly. Their functional ability and quality of life depend mainly on the extent of their neurological impairment. Cognitive and speech deficits and mobility limitations that are often associated with neurological impairment can reduce quality of life significantly. As noted throughout this report, however, judgments about quality of life vary widely depending on the values and perceptions of the observer. Thus, a level of impairment, functional ability, and quality of life that is acceptable to one patient and patient's family may be unacceptable to another patient and family.

Average duration of treatment for elderly people is not known, but data from one registry (153) indicate that over half the patients of all ages starting on TPN at home were still receiving treatment at the end of 1 year; about one quarter of the original patients were dead at the end of the year, and one quarter were alive but no longer on TPN. Survival time varies greatly depending on the patient's underlying disease. As illustrated in figure 8-3, one study found that more than half of the cancer patients (average age 59 years) died within 6 months, and none survived beyond 30 months. In contrast, only about 15 percent of patients with nonmalignant gastrointestinal disorders (average age 56 years) died within 6 months; over half survived at least 3 years, and 15 percent were still alive after 8 years. No information is available about average survival time of patients on tube feeding at home (155).

Nutritional support procedures and equipment used at home are the same as or very similar to those used in hospitals and nursing homes, but home care patients and their families must play a much more active role in the treatment process. People on TPN at home and/or their families must learn to use the pump correctly; start and stop infusion, flush the catheter with saline solution and heparin following infusion; change the sterile dressing at the catheter insertion site; and recognize and respond to problems such as blockage of the catheter or air entering the bloodstream via the catheter (40). Some people on TPN at home mix their own formulas, and they must learn sterile technique and how to measure and combine the ingredients. Others use premixed formulas

Figure 8-3.—Survival of Albany Medical Center Patients on Home TPN With Malignant and Nonmalignant Disease



SOURCE: Oley Foundation, "Nutritional Support and Hydration for Critically and Terminally Ill Elderly," prepared for the Office of Technology Assessment, U.S. Congress, Washington, DC, 1985.

that are usually supplied by a hospital-based or commercial home nutrition service.

Tube feeding at home is less complex than TPN, and sterile technique is not necessary. However, patients and/or their families must learn to use the pump correctly, if a pump is needed; to check the placement of the tube; to monitor the flow rate and temperature of the formula; to flush the tube with water after infusion; and to be aware of potential complications such as aspiration of formula into the lungs. Some patients and/or families who mix enteral formulas themselves need to learn the process, but many patients, probably the majority, use premixed formulas (148).

Nutritional support specialists agree that it usually takes about 2 weeks in the hospital to train patients who are going home on TPN (85,89,101). Training for patients going home on tube feeding usually takes 3 to 6 hours over the course of several days in the hospital. Obviously, the patient's physical, emotional, and mental status affect training time.

There is concern that incentives for shorter hospital stays created by PPS and other cost containment programs restrict the time available for training patients who are going home on nutritional support and ultimately will reduce the safety and quality of home nutritional support for these patients (100). No data are available to determine whether training times have decreased in response to PPS and other programs, and, if so, whether this change has affected the safety and quality of care.

Nutritional Support Personnel for Home Care

From 1969, when the first patient went home on TPN, until 1979, when the first commercial home nutrition service entered the market (212), home nutritional support patients were managed by hospital-based nutritional support teams. Patients usually picked up their supplies from the hospital pharmacy and transported them home. Training was provided in the hospital, and followup visits from visiting nurses were discouraged, because the nurses were generally not trained in TPN or tube feeding and their involvement often caused more confusion than benefit (155).

As home nutritional support became more accepted, pharmaceutical, hospital, and medical supply companies established home nutrition services. These companies provide many services not available from the early no-frills, hospital-based programs, including delivery of supplies, training in the home, followup visits by trained staff, and assistance with third-party billing. Such companies have extended the use of home nutritional support by providing physicians who are not trained in clinical nutrition with access to specially trained nurses, dietitians, and pharmacists to monitor their home patients (155). Some nutritional support specialists and others have expressed concerns about the quality of care provided by some commercial home nutrition services. While recognizing that some of these companies provide excellent care, some analysts worry that physicians may not adequately supervise their home patients who are managed by the companies, and that physicians who are not experienced in nutritional support may delegate too much responsibility for treatment decisions to non-physician staff of the company (61,85,188).

Commercial home nutrition services are not regulated by the Federal Government. It has been suggested that some of these companies do not provide adequate services for their home nutritional support patients and that regulation of the industry may be needed to ensure safety and quality of care.

Standards for home nutrition care have been published by the American Society for Parenteral and Enteral Nutrition. These standards delineate the role of the physician and other nutritional support service providers, the need for written policies and documentation of services, and procedures for patient selection, monitoring, and termination of home nutrition support (9). At present, however, there is no mechanism for enforcing these standards.

Photo credit: Foster Medical Corp

Commercial home nutrition services provide training in the home for nutritional support patients and their families.

Cost and Reimbursement for Nutritional Support in the Home

No precise information is available about the cost of nutritional support at home. Both costs and charges vary considerably, depending on the specific procedures, supplies, formulas, and related services that are used and whether administrative and other costs are included. One OTA contractor estimates that charges for TPN at home typically range from $50,000 to $100,000 per year and that charges for enteral nutrition at home range from $3000 to $12,000 per year (155).

Medicare, Medicaid, and most private insurance cover tube feeding and TPN at home under specified circumstances. Nevertheless, arranging financing for home care patients is one of the most difficult aspects of nutritional support at home, and in some cases, decisions about whether to send patients home on nutritional support depend on the availability of reimbursement (101,171,182).

Medicare funding for tube feeding and TPN at home is provided, as it is in nursing homes, under the Part B prosthetic device benefit. Coverage of home nutritional support under the Part B prosthetic device benefit has three important implications:

1. Medicare reimbursement is provided for 80 percent of covered charges, and another source of payment must be found for the remaining 20 percent (the patient's required copayment);
2. the prosthetic device benefit requires that a patient have "a *permanently inoperative* internal body organ or function thereof" (217), and therefore does not extend to patients who require short-term treatment; and
3. under the prosthetic device benefit, accessories and supplies, such as catheters, pumps, dressings, and nutrient solutions are covered as parts of the device. Initial training for the patient or family is also covered, but since the prosthetic device is expected to replace an inoperative body organ, coverage for continuing services is theoretically unnecessary.

At present, there is disagreement between HCFA and home nutritional support providers about what continuing services are and should be provided for patients on home nutritional support. Providers argue that services are essential for safe and effective treatment for many patients and that Medicare reimbursement under the prosthetic device benefit should include an allowance for continuing services. In contrast, HCFA argues that many commercial home nutrition services provide few services and that current reimbursement, which includes an allowance for initial training, is more than adequate.

Continuing services associated with home nutritional support could be provided under the Part A Medicare home health care benefit. This approach is not workable at present, however, because the home health care benefit covers only short-term or intermittent skilled nursing care. Furthermore, few home health care agencies employ nurses trained in nutritional support, and services provided in the home by dietitians are not covered by Medicare.

The number of patients receiving Medicare reimbursement for home nutritional support has grown rapidly in the past few years. In 1984, in order to contain escalating costs and eliminate what some considered abuses in the program, HCFA issued new guidelines for Medicare coverage of home nutrition. The new guidelines state that patients must require nutritional support for at least 90 days; that reimbursement is allowed only for the simplest (and thus least costly) pump that can be used; and that patients are expected to mix their own formulas unless a physician justifies in writing the need for premixed formulas (8). Each of these guidelines could limit access to appropriate care for some patients. However, OTA is not aware of instances in which elderly patients have been denied Medicare reimbursement on the basis of the guidelines.

HCFA has questioned the charges submitted by some home nutrition services and has proposed new fee screens. Industry representatives object to the way in which these fee screens were developed and to the proposed reimbursement levels (2). OTA has not analyzed the prevailing charges for home nutritional support or the adequacy of HCFA's proposed fee screens.

Medicaid and most private insurers pay for home nutritional support in specified circumstances. Medicaid policies vary among States, but many States require pre-authorization for treatment, and decisions about coverage are often made on a case-by-case basis. Some Medicaid programs follow Medicare guidelines for coverage. Blue Cross and Blue Shield and most other commercial carriers now cover home nutritional support, although policies vary with respect to coinsurance and deductibles.

Public Policy Issues for Nutritional Support at Home

The primary public policy issues arising from the preceding discussion of home nutritional support are potential limitations on access to home nutritional support due to Medicare coverage and reimbursement policies and questions about the quality of care provided by some commercial home nutrition services.

Because of the high cost of TPN and to a lesser extent, tube feeding, most individuals and families cannot afford nutritional support at home without third-party insurance coverage. Some analysts believe that current and proposed Medicare regulations limit access even for long-term treatment. Moreover, since Medicare does not cover temporary or short-term nutritional support at home, some patients who receive nutritional support in the hospital but are discharged before the course of treatment is completed—a situation that is likely to occur more frequently because of incentives for early hospital discharge related to Medicare's prospective payment system —cannot be reimbursed for continued treatment at home. Nor does Medicare cover short-term nutritional support at home for malnourished patients prior to hospitalization for surgery or other treatments.

A related issue is access to nutritional support for patients who are physically or mentally unable to care for themselves and have no family to assist them at home. Although it is sometimes possible to provide 24-hour assistance for such patients in the home (124), the cost of this care is prohibitive for most individuals, and public funding is seldom available for it. As a result, such patients may be placed in nursing homes. Anecdotal evidence suggests that in some cases—especially if the patient requires TPN and there is no nursing home in the area that will accept the patient on TPN—hospital staff may decide not to initiate treatment, and the patient may die.

Although some people advocate increased use of nutritional support procedures at home as a lower cost alternative to providing them in hospitals, others fear that some patients could be kept alive on expensive nutritional support at home with little real benefit to them. These issues are discussed below.

MAKING DECISIONS ABOUT NUTRITIONAL SUPPORT AND HYDRATION

Decisions about the use of nutritional support and hydration are based on clinical, legal, ethical, and financial considerations and reflect the training and preferences of the health care providers involved in the decision and in some cases the wishes of the patient and family. Clinical and financial considerations that affect decisionmaking have been discussed above. Decisionmaking practices vary by setting and are discussed later in this section.

Legal and ethical considerations affect decisions about the use of nutritional support and hydration in all settings. They are discussed at some length here because of their importance in the debate about public policy regarding nutritional support and in individual treatment decisions.

Legal and Ethical Considerations in Decisions About Nutritional Support and Hydration

Legal Cases Involving Nutritional Support and Hydration and Their Implications for Clinical Decisionmaking

Most court cases involving nutritional support and hydration have concerned withholding or withdrawing treatment, but a few cases have dealt with access to treatment and quality of care. The first legal case involving withdrawal of nutritional support and hydration from an adult was decided in 1983. Since then, State courts have ruled on many such cases. Six of the most frequently cited cases are summarized in box 8-A.[8] Each of these cases resulted in a decision that authorized withholding or withdrawal of nutritional support and hydration in certain circumstances. The rulings remain controversial, however, and some legal scholars and others disagree with various aspects of each decision.

From the point of view of clinical decisionmaking, it should be noted that although as of early 1987, there was considerable agreement among court decisions with regard to nutritional support and hydration, this was not true at any time previously. In early 1986, for example, the Massachusetts court ruling that Paul Brophy's gastrostomy tube could not be withdrawn was still in effect, as were a Florida court ruling that Helen Corbett's nasogastric tube could not be removed, and a California court ruling that Elizabeth Bouvia could not refuse tube feeding (see ch. 3). Moreover, a few recent lower court cases have resulted in rulings that tube feeding could not be withdrawn; these decisions were on appeal as of early 1987 (200). Thus, although the most recent court decisions involving nutritional support and hydration have authorized withholding or withdrawal, it is understandable that physicians, nurses, hospital and nursing home administrators, and others remain unsure about the mandates of the law.

Given this uncertainty, health care professionals are likely to provide nutritional support and hydration in cases they are unsure about. This likelihood is enhanced by the inclination of health care professionals to "err on the side of life" and by the fear health care professionals have about negative publicity for withholding or withdrawing nutrition and fluids.

The threat of a criminal murder charge is an even stronger disincentive to withholding or withdrawing nutritional support and hydration. No physician has ever been convicted of murder for withholding or withdrawing these procedures (see ch. 3). However, one district attorney has stated:

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[8] See also the *Bouvia* case (36) discussed in ch. 3.

Box 8-A.—Court Cases Involving Withholding or Withdrawal of Nutritional Support and Hydration

***Barber* v. *Superior Court* (California, 1983)** (21).—In 1982, Clarence Herbert, 55, had a heart attack during routine surgery. He became comatose, and was put on a mechanical ventilator and intravenous fluids. Three days later his doctors and his wife agreed that he should be taken off the ventilator and allowed to die. When the ventilation was removed, he began to breathe. Two days later his doctors and his wife agreed that he should be taken off intravenous fluids, and he died in a few days of pneumonia and dehydration.

A nurse contacted the local district attorney, and the doctors were charged with murder. The district attorney argued that nutritional support and hydration are not medical treatments but simply "conduits for food and water." One complaint of the prosecution was the rapidity of the decision to stop treatment.

Charges against the doctors were dismissed by the Court of Appeals that ruled that nutritional support and hydration are like other medical treatments and may be withheld or withdrawn under some circumstances. The court restated the general rule "that physicians have no duty to continue treatment that is 'futile' or 'has proved to be ineffective' " (16,87; see also ch. 3).

***In re Hier* (Massachusetts, 1984)** (93).—Mary Hier was a 92-year-old nursing home resident who had been a patient in a psychiatric hospital for 57 years before being transferred to the nursing home in 1983. She had been fed through a gastrostomy tube since 1974

In 1984, she was hospitalized because she had pulled out her gastrostomy tube several times, and nursing home staff could not replace it. The nursing home petitioned the court to appoint a guardian with authority to consent to replacing the tube. The lower court refused, and the Appeals Court affirmed that ruling, finding that Mrs. Hier was incompetent to make the decision but that the treatment was not required because it was intrusive and burdensome; because Mrs. Hier had made her opposition to it clear by repeatedly removing other tubes; and because restraints might be required to keep her from pulling the tube out.

After the Appeals Court ruling, the guardian ad litem went back to the lower court. The original judge heard additional witnesses and ordered the tube replaced. It was, and Mrs. Hier lived. However, this lower court decision does not affect the judicial precedent created by the Appeals Court decision (17).

***In re Application of Plaza Health and Rehabilitation Center* (New York, 1984)** (98).—Ross Henninger, an 85-year-old, mentally competent, nursing home resident, decided to starve himself to death. A New York Supreme Court judge ruled that Mr. Henninger had the right to do so and that the nursing home had neither the right nor the obligation to force feed him (see also ch. 3).

***In re Conroy* (New Jersey, 1985)** (94).—Claire Conroy, an 83-year-old, mentally incompetent, nursing home resident, was hospitalized with gangrene of her left leg. Her nephew, who was her legal guardian, refused consent for amputation of the leg and petitioned the court for authority to have her nasogastric tube removed. The petition was granted but immediately appealed, and a stay was granted. Mrs. Conroy died with the nasogastric tube in place. After her death, the Appeals Court ruled that removal of the nasogastric tube would have been homicide, and that "Mrs. Conroy would not have died as a result of an existing medical condition, but rather she would have died, and painfully so, as the result of a new and independent condition: dehydration and starvation" (87). In 1985, the New Jersey Supreme Court reversed this decision, ruling that the feeding tube could have been withdrawn (see also ch. 3).

***Brophy* v. *New England Sinai Hospital* (Massachusetts, 1986)** (38).—Paul Brophy, a 48-year-old man, suffered a brain hemorrhage in 1983 and never regained consciousness. In 1985, his family requested that his gastrostomy tube be removed since he had previously stated on several occasions that he did not want to be kept alive artificially. The Massachusetts Probate Court ruled that the gastrostomy tube could not be removed.

In 1986, the Massachusetts Supreme Judicial Court set aside the lower court ruling that prevented removal of the feeding tube but upheld the lower court ruling that hospitals cannot be compelled to withhold feeding when it violates their ethical principles (38).

***Corbett* v. *D'Alessandro* (Florida, 1986)** (62).—Helen Corbett was an elderly woman who had been in a coma since 1982 and was fed through a nasogastric tube. In 1984, her husband petitioned the court to allow removal of the tube. Mrs. Corbett died with the tube in place after the court hearing but prior to the decision. The court ruled that discontinuing nasogastric tube feeding is barred by the Florida living will statute.

In 1986, the Florida Appeals Court overturned this ruling and found that there is a Constitutional right to privacy that protects an individual's right to refuse nutritional support even when the State living will statute does not allow refusal of nutritional support. The Florida Supreme Court denied a request to review this decision (139).

SOURCE: Office of Technology Assessment, 1987.

> (T)he most fundamental function of the criminal justice system is to protect society from people who would deliberately deprive other people of their lives. Depriving a patient of food and fluid may well make sense in a variety of medical cases. However, when that determination leads inevitably to death, as is the case with deprivation of nutrition and hydration, then the medical profession has crossed over into an area beyond medicine, (and) . . . that practitioner *rightfully* runs the risk of scrutiny and penalty by the criminal justice system (191).

Even if legal charges do not lead to conviction, many physicians fear the impact of such charges on their other patients, their reputations, and their malpractice insurance rates.

In the *Conroy* decision, the New Jersey Supreme Court set out procedures for decisions about withholding or withdrawing nutritional support from an incompetent nursing home resident. The court ruled that a guardian must be appointed; the State Ombudsman for Institutionalized People must be notified and must immediately investigate the case for possible patient abuse; and 3 physicians must agree that the patient has no more than 1 year to live (18,65) (see ch. 3).

Some analysts argue that requiring time-consuming and cumbersome procedures, such as the appointment of a guardian and the involvement of three physicians, discourages decisions to withhold or withdraw nutritional support. They also argue that requiring an investigation by the ombudsman (whose function is to investigate abuse cases) equates withdrawal of nutritional support with patient abuse. This is a clear disincentive for such decisions (18,121)—a disincentive that is applauded by some and regreted by others.

In the first year of the new procedures, only one case was submitted to the ombudsman (see below). Some people believe that families and health care professionals in New Jersey may be making decisions about withholding and withdrawal without following the required procedures, because they are too cumbersome (206).

In June 1987, the New Jersey Supreme Court handed down rulings on two cases that appear to substantially modify the requirements created by the *Conroy* decision. One case concerned Hilda Peter, a 65-year-old nursing home resident who was ina persistent vegetative state and was tube fed. In 1986, the Ombudsman refused to allow removal of her feeding tube because there was no certainty that she had less than 1 year to live (198). In its June 1987 decision, the court determined that since Miss Peter was in a persistent vegetative state, like Karen Quinlan, the life expectancy test required by the *Conroy* decision should not have been applied and that the tube could be withdrawn on the basis of evidence that she had previously expressed a desire not to be maintained in such a condition.

The other case concerned Nancy Jobes, a 31-year-old nursing home resident who was in an irreversible coma and had been tube fed for 6 years. In 1986, a New Jersey court approved her husband's request to remove the feeding tube, but the decision was appealed (96). In its June 1987 decision, the court determined that the family could exercise the patient's right to refuse tube feeding without involvement of the Ombudsman.

A final legal question that may affect decisions about withholding or withdrawing nutritional support and hydration is the liability of nurses for these decisions. While physician liability has received considerable legal attention, the liability of nurses has received less attention. Yet nurses are usually responsible for providing the procedures, and they may have access to more information than the physician about patient and family wishes and the patient's physical and emotional response to providing, withholding, or withdrawing nutritional support (229).

In addition to cases involving withholding or withdrawal, several legal cases have dealt with access to nutritional support and quality of care. While cases on withholding and withdrawal have generally involved tube feeding and nursing home residents, these cases involve TPN and hospital patients. For example, in 1985, a Cook County, Illinois jury awarded $2.3 million in a malpractice case involving a 53-year-old patient who died in 1980. He was receiving TPN in a hospital, and the suit alleged that the physician and the hospital failed to monitor his blood sugar level adequately. He went into a coma when his blood sugar rose to dangerously high levels, and he died 4 months later without ever regaining consciousness (138).

In 1982, a family was awarded $400,000 following the death of a patient with a gastrointestinal disease. The family alleged that the patient's death was caused partly by the physician's failure to provide nutritional support. Some observers expect an increase in such suits (201,208).

The decisions in these cases suggest that nutritional support has become standard care for certain conditions and that procedures such as careful monitoring of blood sugar levels are considered routine when nutritional support is used. On the one hand, these decisions create an incentive for increased use of nutritional support. They could also encourage the formation of nutritional support teams, since patients treated by these teams experience fewer complications than other nutritional support patients (201). On the other hand, PPS is believed by many analysts to discourage the use of nutritional support, as discussed earlier. These contradictory pressures place physicians and hospital administrators in a difficult position in which nutritional support treatments are simultaneously required to provide standard care and avoid malpractice liability, yet may not be adequately reimbursed in some cases.

Legal and Ethical Issues Surrounding the Use of Nutritional Support and Hydration

In connection with nutritional support and hydration, the legal and ethical issues about which there has been the most debate are:

- whether tube and intravenous nutrition and hydration are medical treatments or basic supportive or nursing care,
- whether they are extraordinary or ordinary care,
- whether they are burdensome for the patient,
- whether withdrawing tube or intravenous nutrition and hydration from terminally ill or severely debilitated patients is killing or allowing the patient to die,
- whether "quality of life" should be a factor in decisions about the use of nutritional support and hydration, and
- whether nutritional support and hydration may be withheld or withdrawn from patients who are not terminally ill and not expected to die imminently.

Differences of opinion among people about these issues may reflect: 1) differences in religious and cultural background that affect beliefs about death and the obligation of the individual and society to care for sick and dying people; 2) differences in previous experience with nutritional support and hydration that affect beliefs about the efficacy and risks of the procedures; and 3) other personal emotional and psychological factors that affect the individual's attitudes about starvation, suffering, the value of life, and its relationship to quality of life.

For health care professionals, training, experience, and professional ethics also play a role in determining attitudes. For example, many ethicists have concluded that the distinctions that are sometimes drawn between extraordinary and ordinary care are neither valid nor helpful in decisions about life-sustaining treatment (see ch. 4). Yet some health care providers consider these distinctions important and are reluctant to withhold treatment that their training and experience indicates is ordinary. Nutritional support and hydration are the prime examples.

The symbolism of nutritional support and hydration also affects attitudes, as discussed earlier. Conflicting symbols are particularly difficult. On the one hand, the symbolic relationship between feeding and caring and the image of starving the patient to death encourage a decision to treat. On the other hand, the image of force feeding that may arise, for example, when frail elderly patients must be physically restrained for insertion of a nasogastric tube and to keep them from pulling it out, argues for withholding nutritional support and hydration.

Conflicting attitudes and symbols mean that these decisions are particularly difficult in multiperson settings, like hospitals and nursing homes, and may result in disagreements between staff members. Such a disagreement led to the *Barber v. Superior Court* case (117). A similar situation arose at a Seattle nursing home:

In 1984, several nurses at the Crista Nursing Center refused to withdraw a feeding tube from a 74-year-old stroke patient who was diagnosed as terminally ill and whose physician and family agreed that tube feeding should be discontinued. The family got a court order to have the patient transferred to another facility and to withdraw tube feeding, and the patient died in the other facility. Crista Nursing Center asked for the resignation of one or more of the nurses, but later withdrew the request.

In 1985, at the same facility, several nurses refused to withdraw a feeding tube from an 82-year-old patient, although the patient's physician and family agreed that nutritional support should be discontinued. The nurses were told they would be moved to another nursing unit. The tube was removed, and the patient died. One of the nurses sued the nursing home, the administrator, and the director of nursing, alleging that removing the feeding tube is "illegal, immoral, (and) contrary to (her) religious beliefs" (165).

Conflicting attitudes about withholding and withdrawing nutritional support and hydration make it likely that any federally mandated guidelines about which patients should or should not receive these procedures would result in decisions that run counter to the strongly held beliefs of many people.

Some ethicists fear that allowing withholding and withdrawal in some cases will create a "slippery slope," eventually leading to withdrawal of nutritional support and hydration from handicapped and "pleasantly senile" people (42,87,157, 192). Others argue that decisionmaking based on the "slippery slope" concept sacrifices the welfare of individual patients in order to protect society, which may itself be unethical (52,121).

Legal and ethical debate about nutritional support and hydration has focused on whether they are correctly considered medical treatments or basic supportive or nursing care. This distinction is important for legal purposes because courts have ruled that competent persons have a right to refuse medical treatments and that medical treatments can legally be withheld or withdrawn from incompetent patients, both within certain limits. Many ethicists agree that the distinction between medical treatment and basic supportive or nursing care is valid for ethical analysis. However, some people, including some caregivers in hospitals and nursing homes, who are unfamiliar with the legal and ethical arguments, believe that withholding and withdrawing nutritional support and hydration is wrong, regardless of whether the procedures are defined as medical treatments or basic supportive or nursing care.

One question that is rarely discussed in this context is whether patients have a right to refuse basic supportive or nursing care. Yet many health care providers recognize such a right. It is unclear how recognition of a patient's right to refuse such care relates to the ongoing legal and ethical debate about whether nutritional support and hydration are medical treatments or nursing care and how recognition of a right to refuse nursing care is related to caregivers' attitudes about withholding and withdrawing nutritional support and hydration (232).

The recent decision of the Massachusetts Supreme Judicial Court in the *Brophy* case (38) allowed removal of Mr. Brophy's gastrostomy tube but does not compel the hospital or individual health care professionals to withhold feeding if that would violate their ethical principles. Instead, the court authorized Mr. Brophy's transfer to another setting for withdrawal of the tube. This "conscience clause" in the *Brophy* decision may alleviate concerns of health care professionals and facilities about being forced to withdraw these procedures against their convictions. In some cases, however, conflict is inevitable between this right of health care professionals and facilities, on the one hand, and the right of the patient to refuse treatment, on the other hand.

The conflict arose in the recently decided case of Beverly Requena, a 55-year-old woman with amyotrophic lateral sclerosis (Lou Gehrig's disease), a disease that involves degeneration of portions of the spinal cord, progressive loss of muscle control, increasing paralysis, and eventual death. In June 1986, Mrs. Requena notified the hospital where she was a patient that when her disease progressed to the point where she could not swallow, she would refuse tube feeding. The hospital has a policy against withholding food or fluids from any patient and therefore asked Mrs. Requena to leave. She refused, and the hospital went to court to force her to do so.

In 1986, the Superior Court of New Jersey ruled on the case. The judge stated:

> There is no good outcome to this case. Regardless of any decision made by me or anybody else, one way or another, in one place or another, Beverly Requena will die an unpleasant death in the relatively near future. Going to (another hospital) is a realistic alternative. But if Mrs. Requena goes there, she will experience extra suffering over and above the grim suffering necessarily inherent in her disease and in her choice of no artificial feeding. Requiring (this) hospital to continue to care for Mrs. Requena even though she does not accept artificial feeding is also a real alternative. However, that would entail significant judicial interference with the policies of the hospital and would impose special burdens upon individual health care employees of the hospital (97).

The court ruled, finally, that Mrs. Requena had the right to refuse tube feeding and that she could remain in the hospital until her death. Without any doubt, however, this issue will arise again in other cases.

Although most of the issues discussed above have been the subject of lengthy legal and ethical debate, several other issues with profound legal and ethical implications have received little attention. They are:

- whether tube and intravenous nutrition and hydration must be provided for all patients who would benefit, and, if so, whether the government is obligated to pay for these procedures for people who cannot otherwise afford them;
- whether nutritional support, especially expensive TPN, must be provided for all patients who request it or whose families request it for them, independent of any demonstrable medical benefit to them; and
- whether tube and intravenous nutrition and hydration should be provided in facilities where there is no staff trained to evaluate the patient's need for treatment and provide it safely.

In general, these issues involve questions of access to care and quality of care, as opposed to questions about withholding or withdrawing care.

State Living Will Laws

Living will statutes in 20 States distinguish between nutritional support and hydration and other life-sustaining medical procedures. As of October 1986, statutes in eight States (Colorado, Connecticut, Georgia, Idaho, Maine, Missouri, Oklahoma, and Wisconsin) specify that nutritional support and hydration are *not* among the life-sustaining treatments people may refuse with a living will. In 12 States (Arizona, Florida, Hawaii, Illinois, Indiana, Iowa, Maryland, New Hampshire, South Carolina, Tennessee, Utah, and Wyoming), the language of the statutes is less clear but seems to say that nutritional support and hydration *needed for patient comfort* may not be withheld or withdrawn, implying that procedures that are not needed for patient comfort may be withheld or withdrawn. Living will statutes in other States either allow withholding and withdrawing of nutritional support and hydration or do not refer to them specifically (197).

In States where living will statutes do not allow withholding or withdrawal of nutritional support and hydration, patients may retain basic common law and constitutional rights to refuse such procedures. The 1986 decision of the Florida Appeals Court in the *Corbett* case (62) supports this conclusion.

Conversely, anecdotal evidence suggests that even in States where living will statutes do allow withholding and withdrawal of nutritional support, a patient's refusal of tube feeding may not be honored, as illustrated in the following case:

An elderly California man had a living will and a durable power of attorney drawn up by his lawyer prior to radical neck surgery for cancer. He told his doctors that he did not want nasogastric tube feeding, and they agreed to comply with his wishes. Nevertheless, following surgery, a nasogastric tube was inserted. Despite the efforts of his wife who had authority to make decisions for him through the durable power of attorney, the doctors refused to remove the tube, saying that it was medically necessary. When told about the living will and durable power of attorney, a hospital social worker said, "Oh, that would never hold up in court." The tube remained in place until the man died 3 weeks later (59).

Making Decisions About Nutritional Support and Hydration in Hospitals

Decisions about nutritional support and hydration in hospitals are usually made by a physician, based on his or her perception of the patient's condition and the appropriate treatment for that condition; the physician's decision may also be affected by the opinions of other staff, the patient, and family, and legal, ethical, and financial considerations. Since no information was available at the start of this OTA assessment about how these decisions are made for elderly patients, a survey of nutritional support specialists was conducted for OTA.[9] Findings from the survey cannot be generalized beyond the individual respondents and the hospitals they represent, partly because of the low response rate (about 12 percent) and partly because of bias introduced by the fact that only hospitals that employ nutritional support specialists were included in the survey. Nevertheless, the findings, summarized below, provide some information about decisionmaking in these hospitals and the attitudes of some nutritional support specialists who treat elderly patients. OTA has no information about decisionmaking in other hospitals or about the attitudes of nutritional support specialists who did not respond to the survey or of other health care professionals who are not nutritional support specialists but are involved in decisions about treatment for elderly patients in hospitals.

Survey respondents said that in the hospitals where they work, a team including a physician, a dietitian, and a nurse usually evaluates the patient. Once a decision is made to provide nutritional support, the dietitian usually selects the formula for tube feeding, while the physician and the pharmacist usually select TPN formulas.

Survey respondents indicated that the patient's age per se is not and should not be a consideration in decisions about whether to provide nutritional support. However, almost half said that the patient's mental status is a consideration in these decisions. The reason most frequently cited for this was the likelihood that confused patients will pull out the tube or catheter.

About three-quarters of respondents said that terminal illness is not a contraindication for nutritional support and that nutritional support can contribute to quality of life for terminally ill patients. However, about half said, "Terminally ill patients should not have their lives prolonged by nutritional support," and agreed that nutritional support "should be terminated when other life-support methods, such as respirators, are removed": 31 percent disagreed with the latter statement, and 24 percent of respondents were unsure.

Most respondents disagreed with the statement, "Starvation is an acceptable way of dying for the terminally ill patient." One individual commented, "Dehydration/starvation is a *terrible* way to die! Many times enteral tubes enable medications to be given which contribute to less painful deaths; also other medications which reverse illness."

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[9] During 1985, questionnaires were mailed to about 4,000 members of the American Society for Parenteral and Enteral Nutrition, a professional society that represents physicians, nurses, dietitians, and pharmacists involved in nutritional support. About 470 questionnaires were returned, some of which represent responses of more than one individual, since members at the same hospital submitted joint questionnaires in some cases (115).

About half the respondents said that complications are more common in elderly than younger people; 44 percent said that the rate of complications is about the same, and 2 percent said complications are less common in the elderly. Almost all respondents (93 percent) noted that patients with multiple diseases have more complications than those with a single disease, but the existence of multiple diseases was not seen as a contraindication for treatment. Thus, most of the respondents (91 percent) disagreed with the statement, "Nutritional support is dangerous to use in frail elderly patients."

The last item on the survey questionnaire was an open-ended question inviting comments on nutritional support of elderly patients. Representative comments from nutritional support specialists are cited below:

> "Many elderly people are strong enough to overcome the crisis of illness and go on to resume their lives. It seems discriminatory to withhold nutritional support only because of age."

> "When I first came to this facility, I was amazed at the physical appearance of the geropsychiatric patients. Visible signs of long-term . . . malnutrition were evident. After much persistence and determination (i.e., educating physicians and overcoming resistance from other direct care staff), patients with aggressive nutritional support were showing improved wound healing, increased resistance to infection and increases in visceral protein status."

> "Too often they are left without nutrition support of any kind while being bombarded with other forms of treatment."

> "Nutritional support in the elderly is most frequently overlooked in many instances due to: (1) ignorance of special nutrient needs of elderly patients; (2) lack of knowledgable personnel to consult, evaluate, monitor, and operate necessary equipment; (3) cost of products/equipment; (4) low priority of nutritional problems as compared to physical disabilities; failure to recognize potential relationships."

> "I care for some young patients (less than 65) and reluctantly support them (because they are in a vegetative state). Yet I have treated elderly patients (greater than 75) who are alert, ambulatory, and enjoy life even in the face of terminal illness."

> "I have seen patients that want to die but after nutritional intervention are glad to be alive."

Little is known about the attitudes of patients or family members toward tube or intravenous feeding or the role they usually play in the decisionmaking process. In general, hospitalized patients and their families tend to accept the advice of the physician about necessary medical procedures, and it is likely that most elderly patients and their families accept the physician's recommendation for tube or intravenous nutrition and hydration. However, some hospital patients refuse nutritional support if they are given the opportunity (19).

It is not likely that hospital patients or their families would request or demand nutritional support when it is not proposed by the physician. In the case of patients who cannot eat at all, the outcome—malnutrition and eventual death—is obvious, but for patients who are able to take in at least some food and fluids by mouth, the outcome is less obvious, and many patients and families may not be sufficiently aware of the relationship between nutritional status and outcome to request nutritional support. Nor are they aware of the potential risks involved in nutritional support or the need for careful monitoring once the procedures are initiated.

In many hospitals, formal consent from the patient or family is required for TPN and placement of enteral feeding tubes that involves surgery, e.g., gastrostomy or jejunostomy tubes, but is not usually required for nasogastric tubes (115,155). In some hospitals, nasogastric tubes are placed while the patient is unconscious during surgery, sometimes without the prior knowledge of the patient or family. In other hospitals, these procedures are routinely discussed with the patient or family ahead of time.

Making Decisions About Nutritional Support and Hydration in Nursing Homes

Decisions about the use of nutritional support for nursing home residents are often made in hospitals, and some patients on long-term tube feeding remain in the hospital for prolonged periods.

Since many of the same considerations that affect decisions about nutritional support for nursing home residents also affect these decisions for long-term hospital patients, much of the following discussion is also relevant to them.

Decisions about nutritional support for nursing home residents are ultimately made by the physician who writes the treatment orders. When such a decision is made in a hospital, the physicians may make the decision independently or consult with the patient's family, staff nurses, the hospital dietitian, the social worker, and sometimes the patient. Nutritional support is frequently used on a short-term basis in hospitals, and anecdotal evidence suggests that when a decision is made in the hospital to initiate nutritional support for a long-term care patient, the decision is sometimes made without explicit recognition or discussion of its implications—that a patient may continue on nutritional support for the rest of his or her life, because once the procedures are started, many health care providers are reluctant to withdraw them (63).

When a decision to initiate nutritional support is made while a patient is in a nursing home, the physician is still responsible, but the dietitian and nurses frequently alert the physician to the need for treatment. Anecdotal evidence indicates that nutritional support is sometimes initiated for severely debilitated nursing home residents even when the physician would prefer to withhold it. This situation may occur because one or more staff nurses call the physician repeatedly to report poor intake of food and fluids, and eventually the physician orders tube feeding. In these instances, the nurses may be motivated by: 1) professional standards that require them to report significant changes in the resident's condition; 2) fear that they will be liable for the resident's death if they do not call the doctor; 3) a conviction that it is wrong to let such residents die of malnutrition or dehydration; or 4) their discomfort with watching the resident's condition worsen daily. In fact, some nurses resent a doctor's order to withhold or withdraw nutritional support when the doctor will not be present through the dying process.

Little is known about how or how often decisions are made to withhold or withdraw nutritional support from nursing home residents. In some cases, physicians may make these decisions independently, while in other cases, many individuals are involved, including the patient, the family, one or more physicians, nurses, dietitians, social workers, clergymen, lawyers, hospital or nursing home administrators, and even institutional review boards or ethics committees. Decisionmaking for most nursing home residents probably falls between these two extremes, but the difficulty of the decision and disagreement among those involved sometimes result in these cases being taken to court.

One of the most controversial questions in decisions to withhold or withdraw nutritional support is whether a patient's mental status is or should be a factor in the decision. In one study that addressed this question, physicians at a VA medical facility were asked whether they would tube feed a severely confused 70-year-old woman who was refusing to eat by clamping her mouth shut and spitting out food. Fifty-nine percent of the physicians said they would tube feed this patient, and 41 percent said they would not. In response to a general question, "How often do you attempt to tube feed ward patients with chronic irreversible dementia?" 4 percent of the physician's said "rarely"; 11 percent said "sometimes";

Photo credit: Gretchen Kolsrud

Severely debilitated nursing home residents are sometimes maintained for prolonged periods on nasogastric tube feeding.

41 percent said "most times," and 44 percent said "always" (109).

Nurses' attitudes toward this question were addressed in another study (155) in which the head nurse on each unit in one nursing home was asked which treatments were "too aggressive" for specific residents on her unit. According to the nurses, nasogastric tube feeding was "too aggressive" for 31 percent of the residents. This increased to 46 percent if the same residents became permanently unconscious. Nasogastric hydration was considered too aggressive for 11 percent of residents, increasing to 22 percent if they became permanently comatose. (Although these numbers may seem high to some readers, it is important to note that the procedures were considered appropriate for most residents; for example, nasogastric hydration was considered appropriate for 89 percent of the residents.)

All the nursing home residents from whom the nurses in this study said they would withhold nasogastric hydration had permanent neurological conditions resulting in impaired mental status. These patients comprised only 20 percent of all residents with impaired mental status in the facility, however, and the nurses said that the other 80 percent should receive nasogastric hydration. Thus, the patient's mental status alone was not the deciding factor (155).

A third study (229) compared nurses' and physicians' attitudes about tube feeding nursing home residents. One hundred and twenty-four physicians who were medical directors or house physicians in nursing homes and 157 nurses who were directors of nursing in nursing homes were asked whether they would favor tube feeding for persons described in a series of case examples. The cases varied in terms of the age of the resident (early seventies or late eighties), his or her mental status (occasionally confused or generally confused) and happiness (generally happy and contented or generally unhappy and frustrated). Results indicate that nurses were significantly more likely than physicians to favor tube feeding. There was a trend for nurses and physicians who were Catholic to favor tube feeding, and for nurses and physicians with more years of experience not to favor it, but neither of these results reached significance.

This study found that patient happiness was the strongest influence on nurses' and physicians' attitudes toward tube feeding—both nurses and physicians favored tube feeding more often for patients described as happy than for those described as unhappy. According to the researchers:

> Long-term care provides an opportunity for observing the patient's enjoyment or dissatisfaction. Enjoyment of life is quite variable in nursing home residents: some appear quite happy despite severe limitations, while others have great difficulty accepting even mild impairments. Our results suggest that staff perception of an individual's level of enjoyment plays an important role in ethical decisionmaking (229).

The study found that younger patients (early seventies) were given higher preference for tube feeding than older patients (late eighties). The patient's mental status was a significant factor in the treatment preferences of physicians but not nurses (229).

Use of the patient's mental status as a factor in decisions about whether to use nutritional support and hydration is problematic for two reasons. First is the difficulty of assessing mental status in elderly people (215). Second is the fact that impaired mental status and even coma can be caused by many factors, including malnutrition, dehydration, infections, other treatable illnesses, and medications (111,207). A comprehensive diagnostic evaluation can often identify the causes, but many nursing home residents do not receive such evaluations, thus allowing the possibility that nutritional support could be withheld on the basis of impaired mental status when the impairment was reversible.

Many legal and ethical scholars and clinicians have proposed criteria for identifying patients from whom nutritional support and hydration may be withheld or withdrawn. Some scholars and clinicans would allow withholding or withdrawal only if death is imminent or the patient is so badly deteriorated that nutritional support is physically impossible or extremely painful (22,160), and some would apply these criteria to both competent and incompetent patients (23).

Other scholars and clinicians begin with the premise that competent patients may refuse nutritional support and hydration. For patients who are decisionally incapable or adjudicated incompetent, some would allow withholding or withdrawal of nutritional support and hydration if the patient is terminally ill and the course of his or her disease is unalterable or if the patient is in a persistent noncognitive state (sometimes referred to as irreversible coma or persistent vegetative state) (43,71,127,132,156,205). In 1986, the American Medical Association endorsed this position, stating that it is ethically permissible for doctors to withhold tube and intravenous nutrition and hydration from patients who are terminally ill or irreversibly comatose (6). Some scholars and clinicians would also allow withholding and withdrawal from some severely debilitated and irreversibly demented patients, especially when restraints are required to keep the patient from pulling out the feeding tube or catheter (118,123, 156,227).

Legal and ethical scholars and clinicians who write about withholding and withdrawing nutritional support and hydration define the categories of patients they are discussing very carefully. Many qualify their statements by stressing the importance of any previously stated wishes of the patient and wishes of the family and staff who are caring for the patient. Most add that treatment should be continued if there are doubts about the patient's diagnosis or prognosis. These careful distinctions and qualifications, however, are sometimes lost in informal discussions and media presentations, thus leaving the erroneous impression that some of these scholars and clinicians advocate widespread withholding and withdrawal of treatment from all confused or debilitated elderly patients.

Some legal and ethical scholars, health care providers, and others fear that if nutritional support and hydration can be legally and ethically withdrawn from some severely debilitated or irreversibly demented nursing home residents, the procedures will eventually be withdrawn from many residents (the "slippery slope"). There are no data to test the validity of these fears. On the one hand, there are many problems in the general quality of care provided by some nursing homes (99,216), and it could be assumed that decisions to withhold or withdraw nutritional support and hydration might be made too easily or too often in such facilities. In at least one State, several abuse complaints associated with withdrawal of these treatments have been investigated (136).

On the other hand, despite the many recognized problems in nursing homes, it is clear that nurses and nursing assistants in these facilities frequently succeed in sustaining the lives of very severely debilitated residents for prolonged periods, and many of these direct caregivers resist withdrawal of treatment from residents. Although no approach is foolproof, involvement of these caregivers in the decisionmaking process may provide some assurance that nutritional support and hydration are not withheld or withdrawn too quickly or too often.

An unknown but probably small number of nursing homes have formal policies for decisions about the use of nutritional support and hydration. Some nursing homes have developed limited treatment policies, but one study (135) found that few such policies addressed nutritional support. Those that did address nutritional support recommended hand feeding but did not require tube feeding if oral feeding was impossible. Some facilities require that any limited treatment order must state specifically whether intravenous fluids, TPN, tube feeding, and other treatments are to be provided for the resident (82).

Little is known about the attitudes of nursing home residents or their families toward tube or intravenous nutrition and hydration or about their role in decisionmaking. Anecdotal evidence indicates that some patients fear this form of treatment.

A geriatrician who works in a nursing home finished examining a confused elderly patient who was being fed with a nasogastric tube. As she turned away from the patient, she noticed another of her patients, an alert, well-oriented lady sitting in a wheelchair. The geriatrician asked this lady what she thought about the confused patient with the nasogastric tube. The lady answered that she would never want to be kept alive that way (120).

Many elderly patients may share this lady's feeling. In discussing the attitudes of competent elderly people toward the use of nutritional support for themselves in the future, one physician has stated definitively, "I have never spoken with an elderly patient who requested that a vegetative state be maintained by artificial alimentation" (63). Additional anecdotal evidence that some people fear artificial feeding is the observation that it is sometimes used by physicians and nurses as a threat—"If you don't eat, we will have to feed you with a tube"—in order to convince them to eat.

Family attitudes toward nutritional support and hydration vary widely. Some family members are opposed to prolonging the patient's life with nutritional support and hydration. Yet they may also feel intensely guilty about suggesting that the procedures be withdrawn (64). Because of their ambivalence, they are easily swayed by comments of the physician, nursing home staff, or a trusted clergyman. Other families have religious or moral convictions that prohibit withdrawal of nutritional support.

In nursing homes, as in hospitals, formal consent of the resident or family is generally required for TPN and "invasive" enteral procedures, such as gastrostomy tube feeding. In some nursing homes, formal consent is also required for nasogastric tube feeding. In many facilities, however, formal consent is not required for nasogastric tube feeding.

Many nursing home residents who receive nasogastric tube feeding are confused. In facilities where this procedure can be initiated and maintained for prolonged periods without formal consent, there is no incentive for careful evaluation of whether the resident is decisionally capable with regard to the procedure. As a result, nasogastric tube feeding is initated and continued for prolonged periods for nursing home residents who are assumed to be incapable of making health care decisions—that is, when they say they don't want to be tube fed, their statement is disregarded, yet they have not been adjudicated incompetent; nor has their decisionmaking capacity been formally assessed. Use of a gastrostomy tube for such a patient requires formal consent from a surrogate. For nasogastric tube feeding, even if a surrogate has been designated, the surrogate's consent is not required.

Anecdotal evidence suggests that in some cases, long-term use of nasogastric tube feeding for confused patients may reflect real or perceived difficulties in identifying a surrogate and/or a reluctance of some health care providers to consult with a designated surrogate.

Making Decisions About Nutritional Support and Hydration for Patients at Home

The decision to propose home nutritional support is usually made by the health care providers who have been managing the patient's nutritional support in the hospital. Since the patient and/or patient's family will be responsible for most aspects of the home treatment, however, their attitudes about it and their willingness to learn the treatment procedures are crucial factors in the final decision. Other important factors are the availability of medical backup for emergencies and financial arrangements that permit the patient and family to afford these expensive procedures without severe hardship (155). In addition, if the patient will have primary responsibility for the procedures, he or she must have adequate strength, manual dexterity, visual acuity, and hand-eye coordination to perform the procedures and sufficient cognitive ability to learn and remember them (101). Otherwise, family or other lay caregivers must be available to provide the procedures.

Several patient characteristics could dissuade family members from attempting to manage TPN or tube feeding at home. For example, patients who are medically unstable, bedridden, incontinent, or unable to cooperate in their care for any reason are very difficult to manage at home. Those who pull out their feeding tubes or catheters are also difficult to manage, and while some patients in hospitals and nursing homes have their hands tied to prevent them from pulling out feeding tubes or catheters, it is unlikely that many families would be willing to use such restraints on a regular basis at home.

In many cases, commercial home nutrition services are involved in the decisions about initiating home nutritional support. Some companies have formal patient selection procedures that include assessment of the patient's physical, mental, and emotional status, the availability of family support, the suitability of the home, and the availability of storage space for supplies and equipment. Some companies also require that the patient or family demonstrate mastery of nutritional support procedures in the hospital before being accepted for home care by the company (224).

It is sometimes said that profitmaking companies and clinical enthusiasts who provide home nutrition services now encourage overuse of the procedures or will do so in the future. However, the need for active patient and/or family involvement in home nutritional support minimizes the potential for overuse. Some patients and families may decide against home TPN or tube feeding because they perceive it as complex, uncomfortable, burdensome, or invasive. Thus, one OTA contractor has concluded:

> Although it is always a possibility that in borderline situations (home TPN or enteral nutrition) could be overused by clinical enthusiasts, a natural and substantial brake on such abuse is the strong patient preference to live free of tubes and complex technology. Only when patients and their families experience a quantum leap of better health and well being will they persist with such complex endeavors (155).

In addition, four other factors guard against overuse of home nutritional support:

- Some nutritional support specialists who provide home care services have told OTA that patients should not be sent home on nutritional support if there is no possibility of a "meaningful" existence (155,224). Although "meaningful" is difficult to define, it is clear that these specialists reject the notion of sending patients home on nutritional support who will have very poor "quality of life."
- Nutritional support specialists are conscious of the high cost of treatment and of the concern that these expensive treatments may be overused. Several of them have told OTA that they do not want nutritional support to "be like dialysis," which they believe is used for patients for whom it is futile or inappropriate.
- Individual physicians and hospital-based and commercial home nutrition services assume considerable legal liability for patients they supervise at home. For this reason, they are unlikely to encourage home care for patients who are unwilling or unable to learn and comply with treatment procedures or are otherwise at risk for complications associated with treatment.
- Home nutritional support is reimbursed by Medicare as a prosthetic device, as described below, and level of reimbursement is based on the supplies that are used. An additional fixed sum is included in the overall reimbursement rate for services such as teaching the patient and responding to emergencies. When patients are medically unstable or physically, mentally, or emotionally unable to comply with the necessary treatment procedures or the family is unable or unwilling to assist with treatment, more services may be needed. If these services are provided, the cost of the treatment may exceed reimbursement. If services are not provided, there is increased risk of legal liability.

Though not conclusive, these factors suggest that the potential for overuse of home nutritional support is limited at present.

Many home care patients suffer some anxiety and depression, at least in the first weeks of nutritional support at home, due to the difficulty of treatment procedures; fear about life-threatening complications; loss of the ability to eat and the social interaction that eating often entails; embarassment about the appearance of the indwelling catheter or tube, and anxiety about the cost of treatment. Many home care patients have experienced severe illness, surgery, chemotherapy, or other treatments and may fear recurrent illness and hospitalization. Changes in body image and self concept associated with prolonged dependency on a life-sustaining medical technology can also cause anxiety and depression. Moreover, the need to rely on others for assistance may require complex adjustments in family roles and relationships that cause further anxiety. In fact, patients who are dissatisfied with their quality of life on TPN tend to develop more catheter-related complications, than patients on TPN who are more satisfied with their quality of life (70,101,158, 159,167).

Over the course of weeks or months, most home nutritional support patients, both young and old, accept the technological dependence and are proud of their ability to manage complex nutritional support treatments. Anecdotal evidence indicates, however, that about one-fourth of patients, often those who are older, become depressed and doubt the value of their "technological existence." Supportive listening, small nighttime doses of an antidepressant, and frequent visits from a home nurse may cause dramatic improvement. If depression persists, some clinicians recommend presenting the option of discontinuing treatment, that, in some cases, allows patients to reaffirm their sense of control and their decision to live (155).

A final decisionmaking issue is whether expensive home nutritional support should be provided for all patients who request it or whose families request it for them, independent of any demonstrable medical benefit to them, or conversely whether utilization and/or reimbursement should be limited to patients who benefit from treatment in some defined way. Currently, the complexity of the procedures, professional attitudes, legal and financial incentives, and the lack of public funding for 24-hour home care discourage overuse of home nutritional support. In the future, however, one or more of these factors could change, and society could face demands for treatment from patients for whom the treatments are not medically beneficial. In that situation, could society deny access to nutritional support, and, if so, what criteria would be used for such limitations—would they be based on patient age, physical or mental status, or other criteria?

FINDINGS AND IMPLICATIONS

Accurate information about utilization of tube and intravenous nutrition and hydration is difficult to obtain, but industry data indicate that in 1984 about 1.4 million people of all ages received nutritional support in all settings. Elderly patients represent 40 to 65 percent of the patients who receive nutritional support in hospitals, and almost all those who receive nutritional support in nursing homes; they represent about half of those on tube feeding at home and about 20 percent of those on TPN at home.

Despite the large proportion of elderly people among patients receiving TPN and tube feeding, there has been little research on aspects of nutritional support that may differ for elderly people.

- Physiological changes associated with aging affect nutritional requirements, but nutritional standards for elderly people are not available for many nutrients. The lack of standards complicates the process of assessing nutritional status and identifying elderly patients who may need treatment.
- Changes in body composition and metabolism associated with aging suggest the need for adjustments in nutritional formulas for elderly people, but there has been little discussion of such adjustments in the clinical literature.
- Almost no information is available about indications for use, appropriate treatment procedures and formulas, or efficacy for very old people.

Research in all these areas is needed to improve decisionmaking and quality of care.

The safety, quality, and suitability for intended use of enteral formulas is another concern. Food and Drug Administration review of manufacturing, testing, and marketing practices with regard to these formulas is needed in order to determine the extent of problems and develop recommendations for solving them.

Most debate about the use of nutritional support and hydration has focused on legal and ethical issues involved in withholding and withdrawing of nutritional support and hydration from terminally ill, comatose, and severely debilitated people. Debate has centered around questions about whether nutritional support and hydration are correctly considered medical care, like the other life-sustaining technologies discussed in this report, or basic supportive or nursing care; whether they are ordinary or extraordinary care; whether they are burdensome for the patient; and whether, since all people need food and water to survive, withholding or withdrawing tube or intravenous nutrition and hydration is killing a patient or, in the case of some terminally ill, comatose or severely debilitated patients, allowing a patient to die from his or her underlying disease.

Although these questions remain, there has been a significant change over the past few years in the attitudes of many people about withholding or withdrawing tube and intravenous nutrition and hydration. Less than a decade ago, withholding or withdrawing nutritional support was rarely discussed. Now there is increasing acceptance of the idea that such support may be withheld or withdrawn from some terminally ill and comatose patients. Some people also believe that nutritional support can be withheld or withdrawn from severely debilitated and severely confused patients when the burden of treatment outweighs its benefits. Other people, including some patients, families, health care providers, lawyers, and ethicists, disagree strongly.

As of early 1987, most final court rulings in cases involving nutritional support and hydration from adult patients have held:

1. that tube and intravenous nutrition and hydration are medical treatments;
2. that competent patients can legally refuse such treatments with certain exceptions; and
3. that such treatments can be legally withheld or withdrawn from incompetent patients in carefully defined circumstances.

Prior to these final rulings, lower court rulings in several widely publicized cases—rulings that have since been overturned—had held that nutritional support and hydration could not be legally withheld or withdrawn for a variety of reasons. In several recent cases, lower courts have ruled that nutritional support and hydration could not be withdrawn. Moreover, courts in different States have set out different factors to be considered in such decisions and different procedures for making the decisions. Thus, it is understandable that physicians, nurses, and other health care providers are uncertain about the law in this area. Given their uncertainty and their general inclination to "err on the side of life," health care providers are likely to decide in favor of providing nutritional support in most cases.

Living will laws in many States distinguish between nutritional support and hydration and other life-sustaining procedures. In some States, the legislation specifies that nutritional support and hydration are not among the life-sustaining procedures that can be refused via a living will. Thus, competent adults in those States cannot direct that tube and intravenous nutrition and hydration should not be used for them in the future. The Florida Supreme Court has ruled, however, that people retain basic common law and constitutional rights to refuse nutritional support and hydration at the time the treatments are needed, regardless of restrictions in the State living will statute (62).

Questions about access to nutritional support have received much less attention than questions about withholding and withdrawal. Yet several factors suggest that that tube feeding and TPN may not be provided for some elderly patients who might benefit. Many health care providers who care for elderly people have had little training in nutritional assessment, and some are not aware of the relationship between aging, nutritional status, and acute and chronic diseases. Thus, they may fail to recognize the patient's need for treatment. Lack of nutritional standards for elderly people exacerbates this problem.

Many nutritional support specialists and others believe that Medicare and Medicaid coverage and reimbursement policies discourage the use of nutritional support in hospitals, nursing homes, and in the home. Medicare's prospective payment system is believed by some to limit the use of nutritional support, especially expensive TPN, for hospital patients who might benefit from it. Data to test this assertion, however, are not currently available.

Likewise, Medicare regulations for nutritional support at home are believed by some people to limit access to care for some elderly people. Nutritional support at home is expensive. Thus, for all practical purposes, it is only available to people with Medicare or other third-party insurance to pay for it. Data to determine whether elderly people are routinely denied access to nutritional support at home as a result of Medicare regulations are not currently available.

The interconnection among Medicare reimbursement policies in hospitals, nursing homes, and in the home is a policy issue that has received little attention. While Medicare's prospective payment system is encouraging earlier discharge of hospitalized Medicare patients, limitations on Medicare coverage for nutritional support at home and in nursing homes may restrict access to treatment for some elderly people. Evaluation of these policies should include consideration of their impact on access to treatment across settings.

The efficacy of tube and intravenous nutrition and hydration has not been demonstrated for some diseases, and very little is known about their efficacy in elderly people. Yet the well-documented relationship between malnutrition and poor outcome suggests that critically ill and chronically ill elderly patients might benefit from increased use of these treatments and that Federal policies that discourage their use may ultimately increase the overall cost of medical care for such patients.

Concern has been expressed that severely debilitated and terminally ill elderly patients are or will be given nutritional support at home, even if it does not benefit them, because the procedures are profitable for commercial home nutrition companies. OTA has found no evidence that this is occurring. In fact, many home nutrition companies use rigorous screening procedures that exclude patients who are medically unstable, those who are confused and may pull out feeding tubes or cathethers, and those for whom family support is not available. These screening procedures reflect both the companies' concern about quality of care and their legal liability for patients they serve.

The quality of nutritional support for elderly patients is diminished both by lack of information about their nutritional needs and appropriate nutritional support procedures for them and by lack of staff trained in tube and intravenous procedures in many treatment settings. As of 1984, only about 12 percent of hospitals had a nutritional support team or a nutritional support service group to assist with assessment and nutritional support treatments. Some other hospitals employ individual nutritional support specialists for this purpose, but many do not. Even fewer nursing homes and home health care agencies employ nutritional support specialists.

Lack of trained staff can result in serious complications of treatment, such as coma or death caused by failure to monitor the patient's response to TPN and pneumonia or death caused by failure to check the placement of a nasogastric tube before infusing an enteral formula. Many hospitals, nursing homes, and home care providers recognize the need for increased training for staff who provide nutritional support. Yet Medicare and Medicaid policies that affect reimbursement and staffing requirements in each of the settings do not encourage the involvement of nutritional support specialists, either to provide tube feeding and TPN directly or to train others to provide them.

Very little is known about the relationship between severe dementia and eating disorders. Yet patients who are severely demented present some of the most difficult decisionmaking dilemmas, because they are usually not capable of participating in treatment decisions and because if nutritional support is initiated, they may have to be physically restrained for prolonged periods to keep them from pulling out the tube or cathether. More information is needed about the causes of eating disorders in dementia patients, their nutritional needs, the most appropriate formulas for them, the effect of nutritional support and hydration on their physical and mental status and functional ability, and the effect of withholding or withdrawing these procedures.

Typical decisionmaking practices and the role of the patient and the family in the decisionmaking process vary greatly in different settings. Decisions about the use of tube feeding and TPN at home necessarily involve the patient and family since they must learn and implement the procedures. In some hospitals and nursing homes, all decisions about tube feeding and TPN are made in consultation with the patient or a surrogate if the patient is not decisionally capable. In many hospitals and nursing homes, however, formal consent of the patient, family, or surrogate is required for TPN and tube feeding procedures that involve surgery but not for nasogastric tube feeding, which is the most widely used procedure.

Failure to require informed consent for nasogastric tube feeding is a serious concern when the treatment is expected to be long-term. Many elderly people who receive long-term nasogastric tube feeding are confused, and as indicated, such patients are often physically restrained to keep them from pulling out a feeding tube. This combination of factors would seem to indicate a need for very rigorous decisionmaking procedures that include methods for ascertaining the patient's treatment preferences whenever possible, appointment of a surrogate decisionmaker when necessary, and periodic review of both the need for and the method of nutritional support.

In 1988, the Joint Commission on Accreditation of Hospitals will require hospitals and nursing homes to have an institutional policy for decisions about resuscitation (see ch. 5). In response to that requirement, facilities could choose to develop policies for decisions about all life-sustaining treatments, including nutritional support and hydration. Such policies would have to address any overriding presumptions about the use of tube and intravenous nutrition and hydration in the facility, in addition to the roles of patients, families, physicians, nurses, dietitians, social workers, and others in the decisionmaking process. Existing State law such as living will statutes, family consent laws, and any relevant case law (e.g., in New Jersey, the requirement that the State ombudsman for nursing home residents must investigate cases of withholding or withdrawing treatment from some nursing home residents) would have to be considered in the development of such policies.

At the least, institutional policies for decisions about nutritional support and hydration would allow patients, families, and staff of the facility to know in advance how such decisions will be made. At best, they would involve these individuals in the decisionmaking process in a way that would protect the patient's right to decide but also ensure that decisions to withhold or withdraw these treatments are made cautiously and conscientiously and that they do not constitute neglect or abuse of the patient.

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Chapter 9

Life-Sustaining Antibiotic Therapy

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Chapter 9

Life-Sustaining Antibiotic Therapy

INTRODUCTION

The discovery of antibiotics has been described as the greatest life-saving technological development in the history of medicine. Prior to the development of antibiotics, infectious diseases accounted for over half of all hospitalizations and were responsible for most fatalities in this country. Sulfanilamide was the first antibiotic to be discovered, and physician-author Lewis Thomas has recalled the powerful impression this drug made during his intern years following its introduction in the late 1930s:

> . . . For most of the infectious diseases on the wards of the Boston City Hospital in 1937, there was nothing to be done beyond bed rest and good nursing care. Then came the explosive news of sulfanilamide, and the start of the real revolution in medicine.
>
> I remember the astonishment when the first cases of pneumococcal and streptococcal septicemia were treated in Boston in 1937. The phenomenon was almost beyond belief. Here were moribund patients, who would most surely have died without treatment, improving in their appearance within a few hours of being given the medicine and feeling entirely well within the next day or so (69).

Antibiotics are now widely used to treat a variety of infections caused by viruses, fungi, bacteria, and other protists and are credited with a 10-year extension in average life expectancy at birth. By way of contrast, it is estimated that the successful elimination of cancer would result in only a 2-year extension of life expectancy at birth (31).

Antibiotics are currently prescribed more often than any other class of drugs in the United States and account for more than 25 percent of the $3 billion in annual hospital drug expenditures (52). Some antibiotics can destroy or prevent the growth of only one or a few different kinds of harmful agents, while newer derivatives act against a broader range of pathogens. Antibiotics are used most often to treat mild infections or to prevent infection. This chapter focuses, however, on the use of antibiotics to treat life-threatening infections that, without treatment, would result in death within a few days of onset of the infection.

Antibiotic treatment is generally effective. In addition, it is usually safe, readily available, and relatively inexpensive and painless. For these reasons, and because most people consider antibiotics noninvasive, many health care providers believe that antibiotic treatment is always appropriate when an active infection is present.

Despite this strong presumption in favor of using antibiotic therapy, some health care providers and others believe that there are circumstances in which it is justifiable to withhold life-sustaining antibiotic treatment (18,43,55,78). For example, one physician told about his 96-year-old mother who experienced two strokes a week apart and developed pneumonia following the second. The woman's children asked the hospital staff not to treat the pneumonia, but the hospital staff insisted that they could not "do nothing," and she was given intravenous antibiotics. She survived and was discharged to a nursing home. Her son wrote:

> She can still recognize her family visitors, say their names, and engage in trivial conversation, but her mind is substantially destroyed . . . She is no longer aware of her plight, and expresses no suggestion of despair, but everything she wanted to avoid has happened. In a semivegetating state, she has lost her functional and mental independence. I, the physician son of this woman, weep for my mother and for what has happened to my profession (24).

Although antibiotics are usually effective in the treatment of infections in people of all ages, these drugs cannot cure underlying diseases or disabling conditions that are common among elderly patients. In some patients, a life-threatening infection is superimposed on a terminal illness or an incurable, severely debilitating, chronic disease. Some health care providers and other people believe that in such cases the use of antibiotics to treat the infection sometimes prolongs the dying process or prolongs the patient's suffering unnecessarily.

The few available reports on decisions about antibiotic treatment for terminally ill and severely debilitated elderly people suggest that antibiotic treatment is sometimes withheld from such patients (8,14,33,50,65). Yet these treatment decisions have received much less attention and analysis than decisions about withholding or withdrawing other life-sustaining treatments. This chapter discusses the use of antibiotic therapy for elderly people with life-threatening conditions, the outcomes of such treatment, and what is known about the factors associated with nontreatment.

DESCRIPTION OF LIFE-SUSTAINING ANTIBIOTIC THERAPY

Life-Threatening Infections in Elderly People: The Need for Life-Sustaining Antibiotic Therapy

Despite the frequent success of antibiotics in reversing life-threatening infections, infectious diseases remain a serious problem for elderly people. At a time when medical technologies can support body functions almost indefinitely, severe infection is still one of the few challenges to such interventions. It has been estimated that infections account for approximately 30 percent of all deaths in the elderly population (48). One study based on autopsies found that infection was the second most frequent identifiable cause of death in persons over age 85 (following atherosclerosis) (39).

Some of the life-threatening infections that commonly affect elderly people—bacterial pneumonia, urinary tract infections, infected decubitus ulcers (bed or pressure sores), and iatrogenic infections that sometimes result from the use of medical devices—are described in table 9-1. Any local infection in a seriously ill older person, however, can rapidly spread and become life-threatening.

Various risk factors make people vulnerable to infection, and some risk factors are more prevalent among older people than younger people. One factor that increases the risk of infection is hospitalization. People in hospitals are exposed to a large number of agents that can cause infections. Elderly people are more likely to be hospitalized than younger people, and because of diminished immune function and other factors discussed below, hospitalized elderly patients are two to five times more likely to develop nosocomial (hospital-acquired) infections than hospitalized younger patients (30). Nosocomial infections are often fatal, in part because they are frequently caused by agents that are resistant to antibiotics (79).

A second risk factor for infection—also much more likely for older than younger people—is residence in a nursing home. Communal living, use of urinary catheters, and other factors often associated with nursing home care foster infections. Research indicates that, on average, 15 to 20 percent of nursing home residents have an active infection at any given time (17,26,44).

A third factor that makes many elderly people vulnerable to infections is the presence of multiple illnesses, or comorbidities. The proportion of people with such conditions rises rapidly with age, and it is estimated that 80 to 90 percent of elderly patients with infections also have other diseases including cancer, diabetes, Alzheimer's disease, chronic congestive heart failure, and chronic obstructive pulmonary disease (23).

Other important factors that increase the risk of infections are diminished immune function, diminished physiological function, and reduced physical activity. Immune function declines with age, with various diseases, with some medical treatments (e.g., cancer chemotherapy) (19,29,53), and with inadequate intake of food and fluids that may result from poverty, depression, forgetfulness, mobility impairments, illness, or medical treatments that decrease appetite. Diminished physiological function—for example, a diminished cough reflex—increases susceptibility to infections (8). Reduced physical activity often associated with chronic illness and impaired mobility increases the risk of respiratory infections and decubitus ulcers (19).

A final factor that increases the risk of infection is the use of life-sustaining medical devices

Table 9-1.—Life-Threatening Infections That Commonly Affect Elderly People[a]

Pneumonia is the leading cause of death due to infectious diseases and it ranks sixth as a cause of death for people of all ages in the United States (31). Bacterial pneumonia, along with influenza, is the fourth most common cause of death in elderly people, accounting for 185 deaths per 100,000 persons (40). Mortality rates range from 10 to 80 percent, depending on the bacteria involved and the degree of lung destruction (8).

Nosocomial (hospital-acquired) pneumonias are the most deadly and account for approximately 15 percent of hospital-acquired infections (75). Recent studies suggest that the risk is comparable in nursing homes. Several diseases or condition-associated factors that predispose people to pneumonia are more frequent in the elderly population or affect the elderly more severely—e.g., chronic bronchitis, congestive heart failure, stroke, and dementia (8).

Urinary tract infections are common bacterial infections in older persons, especially women (37). They are the most common infections in hospitalized patients, affecting 1 million patients per year (31). The prevalence of urinary tract infections increases with age, level of care, and decreasing functional capacity. The reasons that urinary tract infections are so frequent in older persons are unknown, but may include prostate problems in men; loss of pelvic support, fecal incontinence, and loss of local bladder mucosal defense mechanisms in women; and use of urinary catheters in both sexes (86).

Infected decubitus ulcers (bed or pressure sores) are associated with immobility, malnutrition, and diabetes, all of which result in poor circulation and skin breakdown. One study found decubiti were the leading source of infection among 532 patients in nursing homes, with a prevalence rate of 6 percent (26). Despite appropriate medical and surgical care, elderly patients with pressure sores associated with bacteremia have a very poor prognosis. The overall mortality associated with sepsis (spread of the infection to the bloodstream) due to pressure sores is approximately 40 percent, and the highest rates (78 percent) have been documented in elderly patients (16).

Iatrogenic infections (infections resulting as a complication of medical treatment) are often related to the use of medical devices. In the late 1970s, for example, an estimated 850,000 infections were related to medical devices, accounting for approximately 45 percent of all hospital-acquired infections in the United States. Infections resulting from the use of life-sustaining technologies such as mechanical ventilators, dialysis machines, and nutritional support equipment constitute a substantial portion of the iatrogenic complications due to medical devices (8,64). During infusion therapy for total parenteral nutrition (TPN) (see ch. 8), for example, infection can be caused by contamination. Infectious bacteria gain access most frequently at the site where the device penetrates the skin (32).

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[a] OTA selected these four infections for emphasis in this chapter because of their prevalence and importance for critically, chronically, and terminally ill, and severely debilitated elderly people.

SOURCE: Office of Technology Assessment, 1987

such as mechanical ventilators (see ch. 6), dialysis equipment (see ch. 7), and devices used to provide total parenteral nutrition (TPN) (see ch. 8). Elderly people constitute a large proportion of the patients who use these technologies.

In addition to increasing the risk of infection, three factors—reduced immunological function, reduced physiological function, and age-associated illnesses such as heart disease, respiratory disease, or cancer—may lower a patient's ability to withstand an infection. Half of the elderly people who die of an infection do so because of the added stress the infection places on their already weakened organs (62). An infection in an individual whose physiological status is already compromised can result in a series of escalating problems, as one woman's experience illustrates:

> **Mrs. W was a 67-year-old widow who lived with her sister in a senior high-rise apartment complex. She underwent a mastectomy about a year ago. At that time, the cancer had spread beyond the breast. After discussion with her doctor, Mrs. W agreed to chemotherapy and radiation despite the poor prognosis. But she did not tolerate the treatments well and suffered much nausea, vomiting, and pain.**
>
> **When Mrs. W developed shortness of breath and difficulty breathing, her sister became very anxious, phoned the ambulance, and demanded that Mrs. W be admitted to the hospital. On admission, Mrs. W was found to have an elevated temperature with an increased pulse and breathing rate. X-rays confirmed pneumonia and numerous cancerous lesions in both lungs. Mrs. W became comatose, was intubated, treated with antibiotics for the pneumonia and admitted to the intensive care unit. Her fever gradually resolved and the pneumonia symptoms improved. Several attempts to wean her from the ventilator, however, proved unsuccessful. The pneumonia, effects of cancer, and her general weakened condition had precipitated complete respiratory failure (8).**

Because of their exposure to a combination of several risk factors, certain elderly people are more vulnerable than younger people or other elderly people to life-threatening infections. Elderly people at greatest risk include:

- critically and terminally ill elderly people who are likely to be hospitalized and to have compromised immunological and physiological status;
- chronically ill, though often clinically stable, elderly people, especially those who may require mechanical ventilation, dialysis, or nutritional support; and
- severely debilitated elderly people with multiple comorbidities, especially those who reside in nursing homes and those who are immobile.

For any of these people, antibiotics are potentially life-sustaining.

Diagnosis of Infection

Infections in elderly people are sometimes difficult to recognize because some elderly patients do not manifest the symptoms of infection that are familiar in younger people. An elderly patient with pneumonia, for example, instead of exhibiting cough, fever, or chills, may instead present nonspecific symptoms such as confusion, anorexia, weakness, or falls. An elderly patient with a urinary tract infection may have no apparent symptoms (19,25,79).

To recognize the presence of infections in elderly patients, caregivers must first be aware that such infections may present differently than the same infections in younger people. They must then be attentive to nonspecific changes in an elderly patient's general physical condition and functioning that may indicate infection. This observation holds especially true for elderly patients with dementia, who are often unable to define or report their own symptoms (19,79).

The identification of the specific bacterial or other agent causing a suspected infection is accomplished via laboratory tests. Many tests used in diagnosis—e.g., the chest X-ray and a culture of secretions coughed up from the lower respiratory tract that are ordinarily used to diagnose pneumonia—are noninvasive.

Obtaining uncontaminated secretions from a patient's lower respiratory tract without using invasive procedures is often difficult, however, because the secretions have to come through the patient's mouth. For this and other reasons, some physicians will treat suspected pneumonia without a culture. If the patient does not respond to the treatment in a few days, a culture may be essential and invasive procedures may be needed to obtain uncontaminated secretions. One procedure, transtracheal aspiration, involves inserting a needle through the patient's neck and trachea and into the lung to withdraw fluid. Some physicians consider such procedures too dangerous to be used in older people (58). Others believe the procedures are safe and useful in diagnosing bacterial pneumonia, especially in severely ill and hospitalized elderly patients (8,11).

Even simple diagnostic procedures that require drawing blood, obtaining a urine specimen, or having a patient cough up sputum may be difficult with elderly patients who are confused as a result of dementia, severe infection, or other illnesses. Severely confused patients may have to be physically restrained during diagnostic procedures, and some patients may have to undergo more invasive diagnostic procedures because of their inability to cooperate with simple procedures.

All types of diagnostic tests are readily available to patients being treated in hospitals, but some tests may not be available or easily accessible for nursing home residents (8,60). Moreover, anecdotal evidence and research findings indicate that in many cases even relatively simple laboratory tests are not used for nursing home residents, and that antibiotic treatment is frequently provided without a diagnostic workup. Three studies of antibiotic use in nursing homes show, for example, that only 11 to 38 percent of residents for whom antibiotics were prescribed had any pretreatment diagnostic tests related to their infections (14,34, 80). Some observers believe that these figures reflect seriously inadequate diagnostic practices (8,80).

Choice of Antibiotic

The choice of a particular antibiotic to treat a life-threatening or other infection depends primarily on the infectious agent (or agents). Other factors that a physician may consider are the nature of the patient's underlying illnesses, his or her history of drug allergies or intolerance, the risk of drug toxicity, and, in some cases, cost (28, 79).

Currently, over 50 antibiotics are licensed for clinical use in the United States (table 9-2). Broad spectrum antibiotics are active against several types of infectious agents, and narrow spectrum antibiotics are active against one or only a few types (56). All antibiotics are fairly specific in their activity, but various antibiotics overlap in their spectrum of activity. Because of this overlap, more than one antibiotic may potentially be effective against a specific infection.

Given the wide range of options for antibiotic therapy and the rapid rate at which new antibiotic derivatives are synthesized, it is difficult to establish a consensus about how best to treat many infections. Clinical guidelines for treating elderly patients with infections do exist (see, for example, app. G), but many physicians base their selection of antibiotics on their own prior experience. The prevalence of any particular strain of bacteria or other infectious agent varies among hospitals, nursing homes, and community settings, so the antibiotic selected for use against a suspected infectious agent may also depend on the

Table 9-2.—Generic Antibiotic and Other Antimicrobial Agents Classified by Family

Penicillins
Natural penicillins
  Penicillin G
  Penicillin V
Penicillinase-resistant
Antistaphylococcal penicillins
  Methicillin
  Nafcillin
  Oxacillin
  Cloxacillin
  Dicioxacillin
  Floxacillin
Aminopenicillins
  Amoxicillin
  Ampicillin
  Bacampicillin
  Cyclacillin
  Hetacillin
  Epicillin
  Pivampicillin
  Talampicillin
Antipseudomonal penicillins
  Carbenicillin
  Carbenicillin indanyl
  Ticarcillin
  Azlocillin
Extended spectrum penicillins
  Mezlocillin
  Piperacillin
Amidino penicillins
  Amdinocillin
  Amdinocillin pivoxil

Amphenicols
  Chloramphenicol
  Thiamphenicol

Aminoglycosides
  Tobramycin
  Gentamicin
  Amikacin
  Kanamycin

Cephalosporins
First-generation
  Cephalothin
  Cefazolin
  Cephapirin
  Cephradine
  Cephalexin
  Cefadroxil
Second-generation
  Cefamandole
  Cefoxitin
  Cefuroxime
  Cefaclor
Third-generation
  Cefotaxime
  Moxalactam
  Cefoperazone
  Ceftizoxime
  Ceftriaxone
  Ceftazidime
  Cefsulodin
  Cefmenoxime

Tetracyclines
Short-acting
  Oxytetracycline
  Tetracycline
Intermediate-acting
  Methacycline
  Demeclocycline
Long-acting
  Doxycycline
  Minocycline

Macrolides and lincosamides
Macrolides
  Erythromycin
  Troleandomycin
Lincosamides
  Lincomycin
  Clindamycin

Sulfonamides and trimethoprim[a]
Sulfonamides and trimethoprim in combination
  Sulfadiazine
  Sulfamerazine
  Sulfamethazine
  Sulfamethoxazole
  Sulfisoxazole
  Trimethoprim
Other
  Sulfacytine
  Sulfadiazine
  Sulfameter
  Selfamethizole
  Sulfamethoxazole
  Sulfapyridine
  Sulfasalazine
  Sulfisoxazole
  Trimethoprim

Miscellaneous antimicrobials
Urinary tract antiseptics
  Cinoxacin
  Methenamine
  Nalidixic acid
  Nitrofurantoin
Other[a]
  Aminosalicylic acid
  Amphotericin B
  Colistin
  Dapsone
  Ethambutol
  Isoniazid
  Metronidazole
  Polymyxin B
  Polymyxin E
  Potassium iodide
  Pyrazinamide
  Rifampin
  Spectinomycin
  Streptomycin
  Sulfoxone
  Vancomycin

[a] These items were adapted from the National Ambulatory Medical Care Survey 1980-81 classification scheme (8).

SOURCE: American Medical Association, *AMA Drug Evaluations*, 5th ed. (Chicago, IL: April 1983).

setting in which an infection is acquired (8,9,21,77). Thus, the choice of an antibiotic may vary from patient to patient, from one physician to another, and from one setting to the next.

To minimize the risk of death from life-threatening infections, antibiotic therapy is frequently initiated before a diagnosis can be obtained. In such cases, empirical treatment is administered—treatment employing antibiotics active against several probable causative agents. When or if the infection is subsequently diagnosed, antibiotics specifically targeted against the identified agent may be used.

Duration of Treatment

In the treatment of life-threatening infections, it is vital to continue antibiotic therapy for an adequate length of time. If the course of treatment is incomplete, some virulent infectious agents may remain, reproduce, and cause a potentially fatal relapse. However, there is no standard duration of antibiotic treatment for life-threatening infections. The appropriate length of antibiotic therapy depends on the type of infection, the specific infectious agent, and the rate of the individual patient's response to treatment (8).

Route of Administration

Antibiotics can be administered three ways: topically, enterally, or parenterally.

1. Topically administered antibiotics are applied to the skin in cream form. Such antibiotics are seldom used to treat life-threatening infections.
2. Enteral antibiotic therapy is administered orally (in tablet, capsule, or liquid form), rectally, or by nasogastric or gastrostomy tubes (see ch. 8). Oral agents are used to treat serious infections only in special circumstances (e.g., when administering parenteral agents is difficult). Ordinarily, oral agents are used to treat infections on an outpatient basis and to complete a full course of therapy in uncomplicated infections.
3. Parenteral antibiotic therapy is therapy administered by intramuscular injection or intravenous infusion. Parenteral therapy is often needed in serious infections to achieve adequate levels of the antibiotic in the patient's blood. Many drugs cannot be tolerated when given by intramuscular injection if more than a few doses are needed per day. For that reason, long-term antibiotic therapy is usually administered by intravenous infusion. Intravenous therapy may also be used when high blood levels of an antibiotic are important, or when the patient has diabetes (56), a common condition among elderly people.

Treatment Setting

For a patient who acquires an infection but remains clinically stable, antibiotic treatment can usually be administered in a nonhospital setting. For a patient whose condition worsens or whose infection is life-threatening, however, admission to a hospital may be necessary. In hospitals, equipment and personnel are available to identify specific infectious agents and to administer antibiotics by any route.

The need for intravenous antibiotic treatment is one of the primary reasons that nursing home residents are transferred to hospitals (8,71). Most nursing homes cannot administer antibiotics intravenously because they do not have an onsite pharmacist to mix the sterile antibiotic with dilutent solution. Furthermore, the number of nursing home personnel authorized to administer intravenous antibiotics is often limited.

According to the 1977 National Nursing Home Survey, there were 340,000 hospitalizations from 1,402,400 nursing home beds in the United States—an annual rate of about 250 hospitalizations per 1,000 nursing home beds (74). That survey does not indicate what percentage of hospitalizations was associated with infections. Findings from other smaller studies (27,35,49,71) indicate, however, that infection is responsible for an average of about 30 percent of hospitalizations of nursing home residents (range: 17 to 56 percent) (8).

In some cases, intravenous antibiotic therapy for life-threatening infections is administered at home. Home intravenous antibiotic therapy is administered to a variety of patients, including patients who acquire a life-threatening infection while dependent on a mechanical ventilator, dialysis, or nutritional support at home and who wish to avoid admission to a hospital. Since patients who are severely ill usually cannot administer their own intravenous therapy, home intravenous antibiotic therapy generally requires the availability of family members or other caregivers who have been trained to provide it.

In hospices, where antibiotics are used primarily to improve patients' comfort, if at all, the use of parenteral antibiotic therapy is discouraged (4). Oral antibiotics are much preferred because they avoid the added discomfort of intramuscular injections or intravenous infusions (8).

UTILIZATION AND COST OF ANTIBIOTIC THERAPY

Utilization of Antibiotics

The information available on utilization of antibiotics is not restricted to their use in treating life-threatening infections. Rather, the data cover all uses of antibiotics, including the more common use of antibiotics to treat mild to moderate infections and prevent infections. The extent of antibiotic use for life-sustaining purposes cannot be determined from available data.

Perhaps not surprisingly, the greatest use of antibiotics occurs in hospitals. Individual hospital surveys consistently report that 25 to 35 percent of all patients receive antibiotics during their hospital stay (70). For up to half of the patients who receive antibiotics in hospitals, the intent is to prevent an infection rather than to treat one (56).

One study of 28 hospitals in Pennsylvania found that the percentage of patients receiving antibiotics increased with patient age, ranging from a low of 22 percent in pediatric patients to a high of 49 percent in patients over age 85 (60). Elderly patients (over age 65) represented 20 percent of all patients in the study but accounted for nearly 40 percent of the patients receiving antibiotics.

In general, elderly nursing home residents receive antibiotics less frequently than hospitalized elderly people, although antibiotics are often used to treat urinary tract infections in nursing home residents (13,80). The percentage of nursing home residents receiving antibiotics at any one time ranges from 8 to 16 percent (26,73, 74,80). It is not known why this variability exists, but it may reflect differences among nursing homes in the proportion of patients who are very old, seriously ill, catheterized, or immobile.

One large-scale study, the 1976 Long-Term Care Facility Improvement Campaign, examined physicians' prescribing patterns in skilled nursing facilities nationwide (73). Most of the facilities were served by community pharmacies. Of more than 1.7 million prescriptions for approximately 284,000 residents in these facilities, 3 percent were for oral or injectable antibiotics. Sixteen percent of the residents were receiving an antibiotic (including preventive antibiotics) at any one time.

Another study, of nursing homes in New York State, found that about 8 percent of residents were receiving antibiotics on the day of the survey. Of these residents, 58 percent had urinary tract infections, 19 percent had lower respiratory tract infections, and 5 percent had skin or subcutaneous tissue infections, including pressure sores (80).

Noninstitutionalized elderly people are not major consumers of antibiotics. The 1980 National Ambulatory Medical Care Survey, a survey of office-based physicians, found that noninstitutionalized patients over age 65 were prescribed drugs to treat arthritis, diabetes, and especially cardiovascular problems more frequently than antibiotics (75). The 1980 National Medical Care Utilization and Expenditure Survey found that antibiotics accounted for only 5 percent of all drugs prescribed for noninstitutionalized elderly people (41).

In 1984, an estimated 14,000 persons were on home intravenous antibiotic therapy (12). It is not known how many of these persons were over age 65, however. Industry sources predict major growth (in excess of 30 percent annually) in the home intravenous antibiotic market.

People with *life-threatening* infections are usually treated in hospitals and are rarely treated at tients (8). Thus, although the information presented here applies to antibiotic use in general, use pattern—the variation in use of antibiotics by setting—holds true for life-sustaining as well as general antibiotic use. Use of life-sustaining antibiotic therapy, like use of antibiotic therapy in general, is greatest in hospital settings and least in noninstitutional settings.

Cost of Antibiotic Therapy

The cost of life-sustaining antibiotic treatment is difficult to determine for several reasons. First, utilization data seldom specify the types of infections treated. Another reason is that studies of the costs of antibiotic therapy do not consistently measure the same costs. For instance, some studies calculate the costs of antibiotic therapy to the supplier, while others focus on the costs to the patient (i.e., what the hospital charges the patient).

In 1982, drug store expenditures for antibiotics totaled almost $0.9 billion. Hospital expenditures for antibiotics that year were over $1 billion, accounting for more than one-fourth of total hospital expenditures for prescription drugs (6).

The cost of antibiotic therapy depends on:

- the type of antibiotic used;
- the amount of antibiotic used (e.g., the daily dosage and duration of treatment);
- the method of delivery; and
- the setting where therapy is administered.

Antibiotic therapy for treatment of life-threatening pneumonia, for example, can cost from less than $30 a day for a relatively simple antibiotic regimen to over $200 a day for a more sophisticated one (8,46).

Some antibiotics that are recommended to treat life-threatening infections are far more expensive than others. Third-generation cephalosporins for the treatment of pneumonia are among the most expensive antibiotics available. Cephalosporins alone account for approximately 1 percent of hospitals' total budgets (38,45).

Recommended antibiotic regimens for elderly patients with bacterial pneumonia, urinary tract infections, infected decubitus ulcers, and TPN-associated septicemia and an example of one hospital pharmacy's charges for the recommended antibiotics are presented in appendix G. Although the figures for charges are illustrative, it is not possible to determine whether they are typical for hospitals in the Nation.

Hospital charges for antibiotic therapy are influenced by the method of delivery. One study of 71 hospitals found that charges added for intravenous administration of antibiotics averaged over $9 per dose (46). In fact, expenses to prepare and administer antibiotics can sometimes exceed the purchase price for the antibiotics themselves (22,66).

The total cost of treating a life-threatening infection in a hospital includes far more than the costs or charges for antibiotic therapy. In a hospital, the total cost also includes diagnostic tests, supportive care, and hospital stay. These additional expenses are substantial (38).

Reimbursement for Antibiotics

Reimbursement for antibiotics by Medicare varies by treatment setting. Under Medicare's Part A prospective payment system (PPS) based on diagnostic related groups (DRGs), hospitals are paid a fixed amount per patient that depends on the patient's diagnosis (see ch. 2). Payment for antibiotics and other drugs provided for hospitalized patients is assumed to be included in the fixed payment for each DRG; there is no separate payment for antibiotics.

In nursing homes, Medicare Part A pays for prescription drugs, including antibiotics, for residents whose nursing home care is paid for by Medicare, provided that the drugs are administered by a health professional. Since Medicare pays for only about 2 percent of all nursing home care, however, only a small proportion of nursing home residents are eligible for Part A reimbursement for antibiotic therapy.

In a physician's office, the patient's home, or any other outpatient setting, antibiotics administered by intramuscular injection are reimbursed by Medicare Part B (Supplementary Medical Insurance). Drugs that are self-administered by the patient or administered by someone other than a licensed health care provider are not covered by Medicare. Intravenously administered drugs, including antibiotics, are not covered by Medicare in any outpatient setting.

Medicaid, the Federal/State reimbursement program for the indigent, pays for most prescription drugs for eligible individuals, although intravenous antibiotics usually require prior approval in States where they are covered (5). A survey of the Medicaid programs in eight States found that seven programs covered home intravenous antibiotic therapy but required prior approval by the Medicaid program office (54). To be eligible, however, patients must have income and assets that do not exceed Medicaid financial eligibility standards, which are low in all States and extremely low in some States.

Little information about private insurance coverage of antibiotics is available. One study found, however, that 15 of 17 Blue Cross/Blue Shield plans in 8 States and 12 other large commercial insurance plans covered home intravenous antibiotics (54).

It is not known how Medicare policies (and the policies of other third-party insurers) that are intended to contain hospital costs) are affecting the use of antibiotics in hospitals. On the one hand, PPS could increase the use of antibiotics in hospitals because the system creates a financial incentive for shorter length of stay, and antibiotics, by treating complications often associated with certain diseases and treatments, can effectively shorten length of stay (8). On the other hand, PPS may discourage hospitals from treating Medicare patients who require long and expensive courses of antibiotics (e.g., after hip surgery or for an infection of the heart lining called endocarditis). For some infections, the level of DRG payment covers only about half the number of hospital days needed for the generally accepted antibiotic regimen (47).

Although home intravenous antibiotic therapy may yield cost-savings for hospitals, the lack of Medicare reimbursement for home intravenous antibiotic therapy probably limits its use with elderly patients. Patients who expect substantially lower-out-of-pocket costs for inpatient care than for outpatient care are unlikely to select outpatient care, regardless of their desire to avoid hospitalization (36,38).

OUTCOMES OF LIFE-SUSTAINING ANTIBIOTIC THERAPY

Antibiotics generally are successful in combatting most types of infections, with patients showing improvement within a few hours or days, and complete cure within a few days or weeks. In the heterogeneous older population, however, the outcomes of antibiotic treatment for life-threatening infections are often unpredictable. Many of the same factors that predispose certain elderly people to life-threatening infections, especially age-related physiological changes and the presence of multiple illnesses, also place them at higher risk of complications from treatment. These factors converge to create a wide range of possible treatment outcomes.

Cure of Infection

The cure of an infection by successful antibiotic treatment usually restores a patient's prior health status. If an elderly patient has been functioning independently before contracting a life-threatening infection, the cure of that infection may mean a return to independence and a personally satisfying quality of life, as illustrated by the following case:

> **Mr. B, a 73-year-old man, had been living independently in the community with the help of his daughter, who brought groceries and helped with chores and cleaning. Following his wife's death from cancer some years earlier, he had discussed with his daughter his desire for a "natural" death and had made out a living will.**
>
> **For some years, he had had cataracts, congestive heart failure, and chronic obstructive pulmonary disease. With medication and medical supervision, however, his condition had remained stable. When Mr. B began to cough up thick sputum and noticed increased shortness of breath and swelling in his ankles, he saw his physician and antibiotics were prescribed.**
>
> **After 5 days, Mr. B's symptoms worsened. His daughter became alarmed and phoned the physician, who recommended immediate admission to**

the local hospital for further diagnostic tests and treatment with intravenous antibiotics. Mr. B protested and despite his weakened condition made it clear that he felt very near death and that he wished no further efforts or heroics to be made on his behalf.

His daughter and physician reassured him that his chance for complete recovery was good, and he was admitted to the hospital, where he underwent X-rays, blood tests, and other diagnostic procedures and received oxygen therapy and intravenous antibiotics. After 7 days of treatment, Mr. B began to improve and to look forward to discharge from the hospital and return to his home. He thanked his daughter and his physician for undertaking aggressive treatment on his behalf, despite his objections (8).

Antibiotic therapy is especially important for chronically ill people receiving long-term mechanical ventilation, dialysis, or nutritional support. Without antibiotic treatment of the iatrogenic infections often associated with these technologies, it would be impossible to restore these patients to a clinically stable condition. Indeed, antibiotics enable these other technologies to sustain lives.

For elderly or other patients who are terminally ill or severely debilitated, cure of an acute infection at best can only restore them to their preinfection health status. When terminally ill patients recover from an infection, their terminal illnesses remain, as do any accompanying pain and suffering. The situation is similar for severely debilitated patients with multiple comorbidities.

Death

When infection is superimposed on terminal illness or severely debilitating chronic disease, the patient's condition may worsen in spite of antibiotic treatment, and death may result. In such cases, the antibiotic treatment may be complicated by the patient's very weakened physiological condition, as illustrated in the following case:

Mrs. G was a 92-year-old widow who had been in a nursing home for 15 years. She had Alzheimer's disease, was blind, and was confined to bed. In addition, she was fed by a nasogastric tube, incontinent of urine and feces, and contracted in a fetal position. Occasionally, her movements suggested to the nurses that she was aware of the activities around her.

Mrs. G's stay in the nursing home had been complicated by repeated urinary tract infections. Her increasing incontinence had led to the insertion of an indwelling bladder catheter. With the catheter in place, antibiotics no longer cleared the urinary tract infections, and the bacteria in the urine were resistant to all but a few of the most powerful and toxic drugs.

One evening while turning Mrs. G, the nurses noticed that her temperature was high, and she was having difficulty breathing due to thick secretions accumulating in her throat. They notified her physician, and Mrs. G was transferred to the hospital. Her first 6 hours there consisted of two complete physical examinations by the intern and resident, chest X-rays, and multiple laboratory studies. Mrs. G was restrained during the vein punctures for these studies. In addition, because she was unable to cough up sputum, a small plastic tube was inserted through her nose into her throat, which caused her to gag, vomit, and choke, aspirating some vomit into her lungs.

The tests revealed pneumonia and an active urinary tract infection. Mrs. G was treated with three intravenous antibiotics. Although she initially improved, fluid in her lungs rapidly developed as a result of all the intravenous fluids that were required to deliver the antibiotics. This condition was aggressively treated with intravenous diuretics and digitalis, which seemed to increase her restlessness. During the night, her restraints became loosened and she fell out of bed, fracturing her hip. Since she had been confined to bed previously, it was decided not to repair the hip surgically.

On the seventh day, the fever returned, and Mrs. G became more short of breath and very restless. Another chest X-ray demonstrated a rapidly progressing pneumonia in her right lung. Because her kidney function was deteriorating, probably from the combination of antibiotics administered, it was decided not to treat the pneumonia with further antibiotics. Mrs. G died 3 days later with progressive pneumonia and kidney failure (8).

Even with antibiotic treatment, older people are more likely to die from infectious diseases than are younger people (8). Pneumonia is perhaps the most notable example. When penicillin was first developed, the mortality due to one form of bacterial pneumonia fell 32 percentage points (from 40 to 8 percent) in the population under age 50.

Although mortality fell 36 percentage points (from 64 to 28 percent) in the population over age 50, it remained at a considerably higher level (23).

Higher mortality in elderly people treated with antibiotics is due primarily to the general decline in physiological and immunological function associated with aging and to complicating comorbidities and disabilities, rather than to age per se (8). Because elderly people vary greatly in their physiological and immunological status, individual elderly patients may respond just as well to antibiotic treatment as younger ones.

Recurring Infection

Another outcome that can result from antibiotic treatment is a less than full cure. Recurring infections can be either relapses caused by the same infection or infection by a different organism. Elderly women in particular tend to have chronic, recurring urinary tract infections despite antibiotic therapy (57). About 80 percent of all patients treated for urinary tract infections develop a recurring infection within 18 months (3). Recurring urinary tract infections in older people often do not present clear symptoms (7). Such infections can occur infrequently, so that they seem to be unrelated, or they can occur very frequently. Broad spectrum antibiotics, in particular, encourage recurrence by fostering the proliferation of strains of bacteria that are resistant to antibiotics.

Superinfection

The human body normally houses many different types of microorganisms, both on the skin and internally. The surface of a normal tooth, for example, harbors approximately 70 different species of bacteria (31). Most of the microorganisms in the body are harmless, and some are quite beneficial, helping with digestion and liberating essential nutrients. Some prevent colonization by other, more virulent, microorganisms by competing for essential nutrients and producing natural antibiotics.

Antibiotics that destroy harmful microorganisms can also destroy microorganisms that are beneficial. When growth of beneficial microorganisms stops as a result of antibiotic therapy, other microorganisms that are not sensitive to the antibiotics may flourish and produce a *superinfection*, a new infection that appears during treatment of a primary infection. The broader the antibiotic that is used, the greater the alteration in the natural flora and the greater the possibility that a single type of microorganisms will predominate, invade, and produce infection. This new infection may be quite difficult to eradicate with the drugs currently available.

Adverse Reactions

Antibiotics are generally safe, and the adverse reactions that do occur are usually mild and cause no permanent damage. Mild diarrhea and nausea are common side effects of many antibiotics. Allergic reactions to antibiotics include skin rashes, hives, itching, wheezing, or difficulty breathing. Nearly all antibiotics, like many other drugs, can cause fever (31).

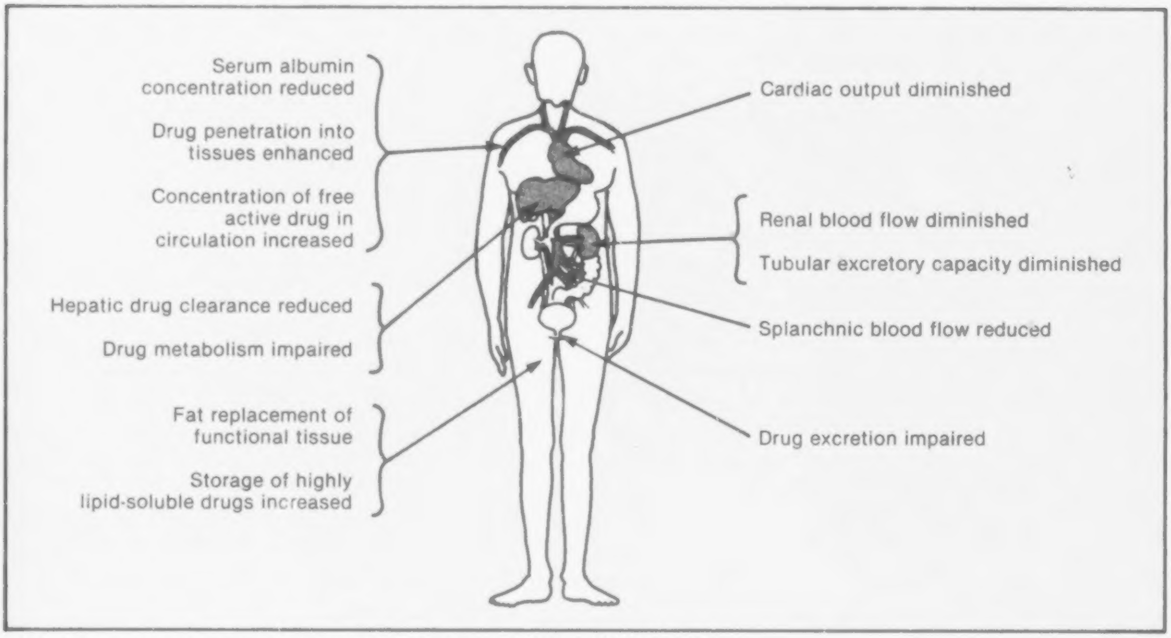
Other, less common, potential side effects of antibiotics include dizziness, hearing loss, seizures, convulsions, hallucinations, coma, and blood clotting problems. Kidney and liver damage in elderly patients are more likely when high doses of antibiotics are used than when low doses are used (2,10,20).

In general, elderly patients are more susceptible and sensitive than younger patients to the toxic effects of drugs. The adverse drug reaction rate is two to seven times higher in older patients than in younger patients (37). A study of patients at Johns Hopkins University Hospital, for example, found that 24 percent of patients over age 80 had adverse drug reactions, compared with only 12 percent of patients aged 41 to 50 (62).

The greater risk of adverse reactions older patients face is explained in part by age-related physiological changes. These changes illustrated in figure 9-1 affect the absorption, distribution, metabolism, and excretion of many medications, including antibiotics in the following ways:

- Reduced liver and kidney function in older patients interferes with the clearance and elimination of some antibiotics from the body.

Figure 9-1.—Age-Associated Physiological Factors That Affect Drug Distribution in Elderly People


Serum albumin concentration reduced
Drug penetration into tissues enhanced
Concentration of free active drug in circulation increased
Hepatic drug clearance reduced
Drug metabolism impaired
Fat replacement of functional tissue
Storage of highly lipid-soluble drugs increased
Cardiac output diminished
Renal blood flow diminished
Tubular excretory capacity diminished
Splanchnic blood flow reduced
Drug excretion impaired

SOURCE: Adapted from I.M. Smith, "Infections in the Elderly," *Hospital Practice* 17(7):69-85, 1982.

- Fat gradually replaces muscle tissue in older people, so drugs that dissolve in fat are stored in the body for a longer period.
- Changes in body size that occur with aging alter the concentration of drugs in the body.
- Gastrointestinal function decreases with advancing age, reducing the solubility of drugs in the stomach and affecting absorption.
- Older people have a decreased amount of the protein albumin in their bloodstream. Since many medications bind to this protein, a decreased amount of albumin may result in a smaller percentage of drug being protein bound, and therefore inactive, and a larger percentage of drug being unbound, or active. This enhances the penetration of certain medications into tissues, while increasing the concentration of free active drug circulating in the bloodstream (62).

As with all physiological changes associated with aging, the timing, extent, and impact of each of these changes differ among individuals.

Patients in whom age-related physiological changes allow the accumulation of toxic concentrations of drugs such as antibiotics will experience adverse reactions. These complications may be especially dangerous when treating life-threatening infections because relatively toxic antibiotic regimens are often used to treat such infections, and elderly patients at high risk of such infections are likely to have compromised physiological and immunological status.

Combinations of various medications ("polypharmacy") also can heighten sensitivity and cause adverse reactions. Many elderly people take a variety of different medications at the same time (61,72). Polypharmacy can influence drug concentrations, decreasing antibiotic binding by enabling other substances to occupy the binding sites of the protein albumin.

The physiological and other factors just mentioned may influence the effect of medications in some elderly patients and alter the dosage required (20). In practice, however, the dose and dose interval are relatively standard for each antibiotic (42). "Usual" or "average" doses of many medications are based on clinical trials that generally involve only young and middle-aged adults.

The altered physiology of many elderly persons is not accounted for in the standards. Thus, it is common for patients to receive identical or similar medication doses regardless of age (61,72).

The Food and Drug Administration recently recommended that dose information in product labeling include instructions for adjusting the dosage for varying degrees of renal impairment. The agency also recommended that a formula for estimating renal clearance, which includes an age factor, be incorporated in the labeling for renally excreted drugs (67,68).

MAKING DECISIONS ABOUT LIFE-SUSTAINING ANTIBIOTIC THERAPY

Decisions about whether to administer antibiotic therapy, unlike those about mechanical ventilation, dialysis, and nutritional support, affect the majority of seriously ill elderly persons and their caregivers (8). Relatively few studies, however, examine the specific factors, aside from clinical considerations, that may be involved in such decisions.

In general, there is very strong support for administering antibiotic therapy to any person with a treatable infection. Many physicians and other health care providers think of antibiotic therapy as ordinary or standard care and, therefore, would not consider withholding it. Antibiotics are generally safe, free of serious adverse effects, and effective. Their administration is usually pain-free and does not drastically alter the patient's lifestyle, and the costs are generally minor.

Because of some or all of these factors, physicians are predisposed toward the use of antibiotics to treat life-threatening infections. This predisposition is strengthened by the fact that they cannot always predict the outcome of withholding antibiotics, since not treating a life-threatening infection may either hasten and ease death or prolong and increase suffering. Thus, the pressures are probably greater to use antibiotics than to use most of the other life-sustaining technologies discussed in this report. One observer has commented, in fact, that the "existence of antibiotics provides the pressure to find an infection to treat—even if infection, while perhaps present, is not the patient's problem" (15).

Since many physicians and other health care providers consider antibiotic therapy ordinary or standard care, they may fear that withholding it will expose them to legal risks. Moreover, some State living will statutes contain wording that is difficult to interpret with respect to antibiotics. The California Natural Death Act, for example, excludes from its definition of procedures that people may refuse with a living will, "the administration of medication or the performance of any medical procedure deemed necessary to alleviate pain" (1976 Cal. Stat. chapter 1439, Code and Health and §7187). The wording of this statute could be interpreted to mean that medications, including antibiotics, are not among procedures that people can refuse with a living will. There is insufficient experience at present to know how California's statute and others like it will be interpreted (63). Even the perception of ambiguity, however, may discourage caregivers from deciding to withhold treatment.

Factors Associated With Decisions Not To Treat

Despite the strong presumption in favor of antibiotic treatment, untreated infections may actually be a frequent cause of death among elderly people in some settings, and some observers suggest that nontreatment of severely debilitated and terminally ill elderly people may be intentional. Only one published study to date has specifically examined factors involved in the withholding of antibiotics (14). Results of that study, based on a review of the medical records of 1,256 residents admitted to 9 Seattle nursing homes in 1973, showed that 190 had one or more episodes of fever associated with infection: 109 of these residents (57 percent) were treated with antibiotics, whereas 81 residents (43 percent) were not. Of the residents treated with antibiotics, 9 percent died. In contrast, 59 percent of those who were not treated with antibiotics died without resolution of their infections.

The factors associated with nontreatment of infections included the resident's diagnosis, physical condition, and mental status. Nontreatment was highest among residents with cancer. Many of these residents died of multisystem failure, and their infection was only a minor contributor to their death, although antibiotic treatment might sometimes have prolonged their lives. Residents who required more nursing care, who were bedridden, in pain, or receiving narcotics were less likely to be treated with antibiotics than residents who required less care. Confused residents were significantly less likely than cognitively normal residents to be treated with antibiotics (14).

Another factor associated with treatment decisions was the resident's marital status. Unmarried residents were least likely to be treated. Widowed residents were treated more frequently, and married residents were treated most. A resident's age was not significantly related to the decision not to treat (14).

Differences in antibiotic treatment decisions also can be related to physicians' familiarity with the nursing home resident. In the study of withholding antibiotics, physicians other than the patient's primary physician were less likely to be aware of the patient's total condition and of any previous plans for nontreatment and were more likely to actively treat an infection. A patient's personal physician, surgeon, or oncologist was less likely to treat a fever. Nurses often determined the degree of treatment a resident would receive. In 20 of the 190 cases (11 percent), nurses did not contact a physician after noticing a patient's fever; this inaction was interpreted by the researchers as a decision not to treat (14).

Data provided to OTA from an unpublished 1984 study of three New York State nursing homes (65) show that 81 percent of residents with potentially life-threatening infections received antibiotic treatment while 19 percent did not. The study found no significant differences between these two patient groups in age, level of education, functional abilities, or marital status and no significant differences in a variety of psychological characteristics, including emotional health and life satisfaction, and in several measures of social support, including the availability of family and friends and the frequency of their visits to the patient. Interestingly, there was also no significant difference in mortality between the group that received antibiotic therapy and the group that did not. In fact, the only significant difference between the two groups was the frequency of the diagnosis of dementia. Residents with a diagnosis of dementia were significantly less likely to receive antibiotic treatment than residents with other diagnoses.

Another unpublished study of nursing home residents cared for by a group of physicians over a 7-year period suggests that both terminal illness and a diagnosis of dementia are correlated with a decision not to use antibiotics for elderly patients (50). As a part of routine treatment planning, the physicians assigned residents to one of four categories to show what treatment they should receive in the event of a life-threatening acute illness:

1. full, unrestricted medical intervention;
2. intermediate—probably full—medical intervention;
3. comfort care/intermediate—primarily restricted to comfort and supportive care, possibly including aggressive medical intervention for a life-threatening episode; and
4. comfort care, and attention to basic medical needs only (50).

Over the years, residents were reassigned to different categories as their condition changed.

Analysis of the characteristics of residents assigned to each category shows that residents in categories 3 and 4 were significantly more likely than those in categories 1 and 2 to have diagnoses of terminal cancer or dementia; about two-thirds of those in category 4 were diagnosed as having dementia. The percentage of residents who were treated with antibiotics also varied significantly among the four categories. For example, half the residents in category 1 who contracted an acute pulmonary infection were transferred to the hospital for treatment of the infection, compared to only 13 percent of residents in category 4 who contracted such infections. Of residents with acute pulmonary infections who remained in the nursing home, 99 percent of those in category 1 received antibiotic therapy, compared to only 50 percent of those in category 4 (50).

Similar findings were obtained for urinary tract infections and infected decubitus ulcers (pressure sores). Forty percent of residents in category 1 who got urinary tract infections were transferred to the hospital for antibiotic treatment, compared to 28 percent of those in category 2 and none of those in categories 3 and 4. Among residents with urinary tract infections who were not hospitalized, 100 percent of those in categories 1, 2, and 3 were treated with antibiotics, compared to 62 percent of those in category 4. Likewise, 100 percent of residents with infected decubitus ulcers in categories 1, 2, and 3 received antibiotics, compared to only 57 percent of those in category 4 (50).

Overall mortality due to acute pulmonary infections was only slightly higher among persons in categories 3 and 4 (29 and 22 percent respectively) than among persons in categories 1 and 2 (19 and 15 percent respectively). This was true despite the fact that a much higher percentage of residents in categories 1 and 2 received antibiotic therapy. The researchers concluded that a certain percentage (roughly 20 to 25 percent) of all pulmonary infections among nursing home residents will be fatal, with or without antibiotic therapy. They hypothesized that most of the fatal pulmonary infections occurred at times when the affected residents were particularly vulnerable because of their underlying diseases (50).

Anecdotal evidence suggests that settings of care may influence decisions about antibiotic therapy and that physicians are likely to implement more aggressive treatment in a hospital than in a nursing home (8). In an interview for OTA, one physician stated:

> [In the hospital,] the house staff and nursing staff are all geared primarily to use all methods possible to help patients, who may have already been started on antibiotics at the time they reach the hospital. Things can go fast and it is hard to stop something once you have started. I suppose there are psychological pressures on all of us to use the weapons that are readily available in the hospital. In the nursing home, those weapons are not immediately available and there may be just a little less pressure to do everything . . . It is easier in some ways to withhold treatment in a nursing home because you don't have to involve as many people in the decisionmaking and convince them if they are not convinced. You can make the decision on your own (8).

The type of infection a patient has may also influence treatment decisions. In general, it is recommended that pneumonia, urinary tract infections, and decubitus ulcers be treated with antibiotics when the symptoms are distressing to the patient (8,55). Untreated decubitus ulcers are frequently very painful. In contrast, untreated pneumonia may cause only mild discomfort due to shortness of breath. Some observers have even suggested that death from pneumonia may be preferable to continuation of a life with severe disabilities:

> Pneumonia may well be called the friend of the aged. Taken off by it in acute, short, often painless illness, the old escape those "cold degradations of decay" that make the last state of all so distressing (51).

The Decisionmaking Process

Very little information is available about the decisionmaking process with regard to life-sustaining antibiotic therapy. Anecdotal evidence suggests that the physician often acts alone in making a decision about whether or not to treat a life-threatening infection. He or she may consider the opinions of nurses, the patient and/or family, and other caregivers. There are no data, however, to determine how often any of these individuals are consulted about such decisions.

Explicit written consent from the patient or surrogate usually is not obtained for the administration of antibiotics. The primary reason for this is that antibiotic therapy does not involve surgery and is generally considered noninvasive. As a result, hospitals, nursing homes, and other health care facilities usually do not require physicians to obtain a patient's or surrogate's written consent for it. In addition, obtaining written consent can be time-consuming and may interfere with prompt initiation of treatment that is frequently needed to ensure efficacy.

Anecdotal evidence indicates that in some cases, even verbal consent of the patient or surrogate is not obtained before antibiotic therapy is administered. This may occur because physicians and other health care providers assume, perhaps rightly, that patients with treatable infections want to receive antibiotic therapy. It is also sometimes said that a patient's consent for treatment of an infection is implied by his or her admission to a hospital.

It is not known how often life-sustaining antibiotic therapy is withheld without either written or verbal consent of the patient or surrogate. The three studies cited earlier on factors associated with nontreatment do not discuss this question (14,50,65). It is also not known whether physicians and other health care providers who believe that the administration of antibiotics does not require explicit consent also believe that life-sustaining antibiotic therapy may be withheld without explicit written or verbal consent of the patient or surrogate.

One very difficult aspect of decisionmaking with regard to life-sustaining antibiotic therapy is that some severely debilitated elderly people for whom antibiotic treatment might be used are incapable of participating in the decisionmaking process because of varying degrees of cognitive impairment. Such people are more likely to be kept alive by nutritional support and antibiotic treatment for intermittent infections than to need or receive more dramatic life-sustaining treatments like resuscitation and dialysis (59). Decisionmaking aids, such as the living will and durable power of attorney (see ch. 3), are often of little use with these patients because the patients often have been cognitively impaired for a long time and are unlikely to have given specific advance directives about their care while they were still able. It is frequently with these patients that physicians must wrestle with the decision of when or whether to "switch gears" from cure to supportive care and withhold life-sustaining antibiotic therapy.

One physician's description of his isolation in reaching these decisions generated numerous letters in response and seemed to touch an exposed nerve in the medical community:

> . . . Elsa Toivonen, 83 years old. Confined to the nursing home ever since her stroke 3 years ago. Bedridden. Aphasic [not able to verbally communicate]. I remember admitting her to the hospital after her stroke, . . . and those first few hospital days in which I aggressively treated the pneumonia that developed as a complication, giving her intravenous antibiotics despite her apparent desire to die. "Depressed," I had thought. "She'll get over it. Besides, she may recover substantially in the next few weeks." She recovered from the pneumonia, but she remained paralyzed and aphasic. For the past 3 years she had lain curled in her nursing-home bed, a grim reminder of the "power" of modern medicine . . .
>
> . . . Wasted away to 69 pounds, decubitus ulcers on her back and hip, peering at me from behind her blank face—I'm used to all that from my monthly rounds. But this morning there is no movement of her eyes, no resistance to my examination, nothing to indicate that she's really there. There is little more to the history of Mrs. Toivonen's fever than what I gathered [from the nurse] over the phone, and Mrs. Toivonen's aphasia precludes much of an interview. My examination is brief, directed pointedly towards the usual causes of fever in elderly people . . .
>
> Essentially alone, foggy from tiredness in the middle of the night, I will make decisions that will essentially mean life or death for this poor old woman . . . There in the middle of the night I consider doing "everything possible" for Mrs. Toivonen: transfer to the hospital, intravenous lines for hydration and antibiotics, and even thorough laboratory and X-ray evaluation, twice-daily rounds to be sure she is recovering, more toxic antibiotics, and even transfer to our regional hospital for evaluation and care by a specialist. None of it is unreasonable, and another night I might choose just such a course. But tonight my human sympathies lie with Mrs. Toivonen and what I perceive as her desire to die . . .
>
> But I can't just do nothing, either. My training and background are too strong. I do not allow myself to be consistent and just go home. Compromising (and ultimately making a decision that makes no ethical sense at all), I write orders instructing the nursing staff to administer liquid penicillin, to encourage fluid intake, and to make an appointment with my office so I can reexamine Mrs. Toivonen in 36 hours . . . Driving home, I wonder why practicing medicine is so often dissatisfying . . .
>
> . . . The problem is simply too difficult for me as a single human being to face in a conscious way . . .

> For my part, the underlying irrationality of my decision has gnawed at me; the life-and-death importance of my actions has kept me awake at night; the guilt and depression of never really knowing whether I have acted properly have been overwhelming (33).

Very few guidelines have been proposed for when, if ever, it is appropriate not to treat infections. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research found "no particular treatments—including such 'ordinary' hospital interventions as antibiotics—to be universally warranted and thus obligatory for a patient to accept" (55).

Wanzer and associates (78), in their classification of levels of care for "hopelessly ill patients" determined that antibiotic treatment should generally be provided for all patients except those in their 4th category, general medical care. According to the classification system, patients in that category "are usually those clearly in the terminal phase of an irreversible illness" (78). With regard to patients who are in a "persistent vegetative state" (i.e., "the neocortex is largely and irreversibly destroyed, although some brain-stem functions persist"), the authors state:

> When this neurologic condition has been established with a high degree of medical certainty and has been carefully documented, it is morally justifiable to withhold antibiotics . . . , as well as other forms of life-sustaining treatment, allowing the patient to die. This obviously requires careful efforts to obtain knowledge of the patient's prior wishes and the understanding and agreement of the family (78).

With regard to patients who are severely and irreversibly demented, they conclude:

> It is ethically appropriate not to treat intercurrent illness except with measures required for comfort (e.g., antibiotics for pneumonia can be withheld) (78).

With the exception of these guidelines, however, the medical literature rarely discusses when, if ever, it is appropriate not to treat infections. This may be due in part to the elusive nature of "quality of life." Subjects like "how to treat pneumonias," "appropriate care for decubitus ulcers," or "recommended antibiotic therapy for urinary tract infections," are discussed at length in infectious disease journals and texts and are fairly straightforward. It is much more difficult to grapple with the question of whether or not to treat a patient who is terminally ill or severely debilitated. Since there has been so little discussion of this question in the clinical literature there are few criteria or guidelines for making these decisions.

FINDINGS AND IMPLICATIONS

Antibiotics are used most often to treat mild infections or to prevent infections, and no data are available to determine how many people of any age receive antibiotics for life-threatening infections. Antibiotic use for all purposes is greatest in hospitals and lowest in outpatient settings. Hospital surveys report that 25 to 35 percent of patients in the United States receive antibiotics during their hospitalization (70). The percentage of patients receiving antibiotics in the hospital increases with age; in one study, persons over 65 years of age represented 20 percent of the total patients but accounted for nearly 40 percent of patients receiving antibiotics (60).

Research in nursing homes shows that 8 to 16 percent of the residents are receiving antibiotics at any one time (26,73,74,80). A smaller percentage of persons receive antibiotics at home (41).

Life-sustaining antibiotic therapy is usually administered intravenously and may necessitate admitting a patient to a hospital, where a full range of support personnel and medical services are available. Such therapy must be initiated promptly if it is to be effective. Thus, empirical treatment with an antibiotic active against many different infectious agents is often initiated before a definitive diagnosis can be made.

Although life-sustaining antibiotic therapy often must be initiated before a definitive diagnosis is made, the usual and recommended medical practice is to perform laboratory tests to identify the cause of the infection as quickly as possible. When the infectious agent is identified, antibiotics specifically targeted to it may be used. Research indicates that such tests are usually performed for hospitalized patients but are frequently omitted in the management of suspected infections in nursing home residents (80). Some observers believe that this constitutes inadequate medical care for these residents, and they have proposed guidelines for diagnosing infection and selecting antibiotics for patients in nursing homes (8,80).

The use of life-sustaining antibiotic therapy with elderly people involves special considerations. Infections sometimes present different symptoms in elderly people than in younger people. Caregivers must be aware of this possibility and attentive to nonspecific symptoms, such as confusion, weakness, or falls, that may indicate the presence of an infection. At the same time, more research is needed on the presentation of infection in elderly people.

The outcomes of life-sustaining antibiotic treatment of elderly patients range from complete cure to death. Antibiotics are usually effective in curing infections. However, they can neither eliminate nor alleviate preexisting illnesses in chronically, critically, or terminally ill or severely debilitated elderly people.

Elderly patients as a group are at higher risk of developing adverse reactions to antibiotic therapy than are younger patients. Age-related physiological changes affect the way drugs concentrate in the body and can allow accumulations to toxic levels. Most drug dosages are standardized and do not account for the higher blood levels of a drug that may result from an elderly person's altered metabolism. At present, the Food and Drug Administration does not require specialized dosages for elderly persons, although it has recommended that a formula for estimating renal clearance, which includes an age factor, be incorporated in the labelling for renally excreted drugs. More research is needed on the effects of physiological changes associated with aging on absorption, distribution, metabolism, and excretion of antibiotics and the implications of these effects for appropriate antibiotic therapy.

Despite these considerations, antibiotics remain among the least complex and least expensive life-sustaining technologies. Because many physicians consider antibiotics ordinary or standard treatment, their decisions to use them in the treatment of life-threatening infections are often automatic. Clinical criteria, rather than patient's or surrogate's wishes, are often their primary considerations. In most cases, the patient's or surrogate's explicit written consent is not obtained prior to the administration of antibiotic treatment. It is not known how often verbal consent is obtained.

Some people believe that requiring explicit informed consent (written or verbal) for antibiotics would help ensure that the patient's or surrogate's wishes are respected in the decisionmaking process. Others believe that requiring explicit informed consent, especially written consent, would create a time-consuming obstacle to prompt treatment and that explicit informed consent is not necessary in most cases of life-sustaining antibiotic therapy.

Many of the elderly patients being considered for life-sustaining antibiotic treatment are severely debilitated and incapable of making treatment decisions. Decisionmaking aids like the living will are rarely of use to these people, who often have been incapacitated for a long time and are unlikely to have given specific prior directives regarding their care. For these patients in particular, antibiotic treatment decisions may be strongly influenced by the setting of care. Infections are often aggressively treated in hospitals, where there are pressures to use all of the measures that are readily available. In nursing homes, where medical resources are less readily available, there may be less pressure to use antibiotic therapy.

Living will statutes in some States contain wording that may be perceived to exclude antibiotics from the life-sustaining treatments that people may refuse with a living will. The ambiguous wording in these statutes could be revised to clarify their intent. This might reduce caregivers' uncertainties about legal risks, thus encouraging them to rely on advance directives in making treatment decisions.

Current Medicare policies favor management of life-threatening infections in hospitals and may discourage some patients from receiving therapy at home. A consequence may be higher antibiotic use and expenditures in hospitals. Although Medicare reimbursement for antibiotic therapy administered at home could encourage use in that setting, no estimates are available of the number of elderly patients now treated in hospitals who could receive antibiotic therapy at home.

Few guidelines or criteria have been developed to help physicians decide when, if ever, nontreatment of a life-threatening infection is appropriate. Likewise, few hospitals or nursing homes have policies about the procedures to be followed in making such decisions. Some observers have expressed concern that these factors place overwhelming responsibility on the shoulders of the individual physician (33). Others have noted that the lack of guidelines and policies allows wide variability and individuality in decisionmaking (8). One OTA contractor concluded that guidelines or criteria for decisionmaking could have both good and bad consequences (8):

> Good consequences will result from providing a structure for physicians to consider carefully the goals for starting antibiotic therapy and to discuss with the patient and family all aspects of the decision to treat or not treat with antibiotics. Bad consequences will result because rigid guidelines (especially if enacted in statutes or codes) will severely limit the individual capabilities of the best physicians, already sensitive advocates for their patient's wishes, to practice the art of medicine (8).

Professional associations could develop guidelines for decisionmaking to encourage communication among physicians and other professional caregivers about factors that should be considered in such decisions. Process-oriented guidelines in hospitals, nursing homes, and other health care facilities could delineate more clearly the role of the patient or surrogate in the decisionmaking process and the circumstances in which explicit consent, either written or verbal, should be obtained before antibiotic therapy is initiated or withheld.

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Chapter 10

Manpower and Training

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Chapter 10

Manpower and Training

INTRODUCTION

The five medical technologies discussed in the preceding chapters represent an impressive variety of devices and substances capable of sustaining life. This chapter focuses on a crucial element that is common to them all—dependence on qualified personnel. The chapter examines factors that influence the supply, the training, and the interrelationships of pertinent health professionals with each other and with their patients—all of which influence the accessibility, quality, and cost of health care for elderly persons for whom life-sustaining technologies are, or might be, used.

The professions involved in the care of life-threatened elderly people are numerous, diverse, and *changing*. The advent of new technologies to sustain life has been accompanied by major expansion of training initiatives and career opportunities, both inside and outside the traditional health professions. Within the professions of medicine and nursing, new specialties and subspecialties have developed, and members of the traditional professions and older specialties have had to acquire new knowledge and new skills. In addition, entirely new health professions have been created. In the past 25 years, tens of thousands of people have moved into "technology-dependent" health professions.

During roughly the same period, recognition of the vast and growing numbers of elderly persons in the U.S. population has created a new focus within the health professions. After a consciousness-raising characterized as "almost a revolution" (93), there is now wide agreement among health professionals that "the elderly are not simply old adults" (129), and a significant commitment has emerged within medicine, nursing, and some allied health professions to redress past neglect of the elderly (89).

Another important development is the growing recognition that today's health professionals need to be prepared to deal with the ethical, legal, and economic constraints that modern medical technologies bring to the fore. There is increased attention to the fact that decisionmaking about life-sustaining technologies demands caregivers who understand and are sensitive to ethical and humanitarian principles. These caregivers must not only know their profession and understand the patient population, they must show good judgment and caring, respect for patients' wishes, communication skills, ability to work as part of a health care team, and readiness to help even when healing is no longer possible.

The health professionals who care for elderly patients receiving life-sustaining technologies come from diverse professions and specialties that, very broadly, represent two orientations: the generalist approach of primary care and, in contrast, the more focused approach of critical or intensive care. Specialized care of the elderly, i.e., *geriatrics*, is closely aligned with adult primary care.

Health professionals who specialize in primary care and geriatrics, on the one hand, and those who specialize in critical care, on the other hand, increasingly meet in the clinical arena. Relationships between them, however, have received little attention. One purpose of this chapter is to explore these relationships and how they may affect the care elderly patients receive. The focus is on the setting in which most of this interaction occurs, i.e., the acute care hospital.

Federal policies and programs have important direct and indirect effects on the health professions. Federal manpower policies, for example, include explicit measures to influence the overall supply of health professionals as well as measures to change their specialty and geographic distribution. Other Federal policies and programs, including Medicare, influence the supply, specialty, and geographic distribution indirectly. Federal regulations regarding certification of hospitals and nursing homes by Medicare, for example, impose standards for the number and skill levels of caregivers that Medicare-certified institutions employ. Federal policies regarding reimbursement for patient care affect the demand for certain procedures and technologies; these factors in turn indirectly influence the specialty choices and career opportunities of health professionals (72,74). Some of these policies have favored the development of medical technologies and medical specialties over primary care. Other Federal programs and policies have been specifically directed to improve primary care for elderly people and access to it.

Some important manpower and training questions, such as questions about how medical expertise and responsibilities are best organized, are only secondarily related to public policy. Whether or not geriatrics warrants status as a separate medical specialty, or whether nurses should provide respiratory therapy, for example, are questions for knowledgeable professionals to decide. A profession's decisions about what its members must know and what they may do, however, have important ramifications that fall squarely within the interest of both policymakers and patients. Furthermore, Federal policies that affect health professions training and health care reimbursement have an impact on the professions' ability to implement their intended policies.

CAREGIVERS[1] AND THEIR ROLES

The medical technologies considered in this report involve an enormous array of professions and individuals. This chapter focuses on the physicians, nurses, and allied health professionals who provide direct patient care, especially in hospitals. Essential behind-the-scenes professionals, including researchers and engineers, hospital administrators, and others, are beyond the scope of this discussion. Similarly, the importance of psychologists, clergy, lawyers, and other professionals who serve counseling and coordinating functions is recognized but not addressed.

In some settings, nonprofessional staff contribute to the care of seriously ill elderly persons who may be candidates for life-sustaining treatments, and, at times, they contribute to treatment decisions. In nursing homes, where aides constitute by far the largest proportion of caregivers (78), responsibility for decisions about transferring a resident to a hospital for the initiation of life-sustaining treatment belongs to professional nurses and physicians. However, professional staff are often unaware of changes in a resident's condition unless notified by an aide. So, while nonprofessional staff are not routinely or intentionally involved in treatment decisions, they sometimes play a role.

Another major category of caregivers, especially for patients in their own homes, consists of family members, friends, and patients themselves. These lay caregivers provide routine care and also may make critical decisions about when to call professional help. OTA acknowledges the importance of family and other nonprofessional caregivers—and their increasing importance as more life-sustaining treatment moves outside the hospital. The availability, training, and supervision of lay caregivers and their need for social and financial support are discussed in chapters 5 through 9.

Physicians and, to a lesser extent, nurses most often play the key roles in making recommendations about implementing life-sustaining treatments. However, "physicians and nurses" includes a range of actors such as primary care physicians, specialists and subspecialists; the patient's longtime personal physician as well as consultants the patient may never meet; highly trained professional nurses as well as practical nurses; individuals with extensive experience and others still in training. In addition, many categories of allied health workers are involved in the delivery of life-sustaining technologies. Ensuring that the necessary combination of expertise (whether this is embodied in a single individual or a health care *team*) is available for all patients is a major concern.

Specialists in Primary Care and Geriatrics

Primary care practitioners are those health professionals who have initial contact with and ongoing responsibility to the patient. Most often, adult primary care is provided by a physician who is a specialist in internal medicine or family practice. In some settings, especially long-term care institutions, professional nurses and nurse practitioners may provide primary care. The functions of primary care professionals include identifying and managing illness and—especially important in the case of patients with complex conditions and needs—referral of patients to other health professionals or services. Relative to other specialists who may be drawn into a case, whose expertise relates to one or another organ, system, or disease, primary care physicians and nurses have a more holistic perspective and often broader knowledge of the patient, sometimes through a relationship established over many years.

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[1] The term "caregivers" is used to refer collectively to professional personnel and other persons who provide patient care.

A *geriatrician* is a physician who possesses special knowledge of geriatrics or geriatric medicine, i.e., "the medical knowledge of physical disability in older persons—including the diagnosis, treatment, and prevention of disorders" (148). Although most geriatricians are trained as primary care practitioners, a geriatrician is seldom the "primary" physician to be consulted. *Gerontologic nurses* and *geriatric nurse practitioners* are the other major groups of health professionals that specialize in the care of the elderly.

Specialists in geriatrics and gerontology have a broad approach to the patient that includes psychosocial as well as biomedical characteristics, and interest in preventing illness and disability as well as restoring maximum functioning and health. In medicine, the breadth of geriatrics and the resulting overlap with better established medical specialties contributes to ambiguity about the proper disciplinary boundaries (138) and the optimal relationships between geriatricians and other physicians.[2]

It is important to recognize that the vast majority of primary care practitioners involved in the care of elderly patients are not specialists in geriatrics or gerontology. Some physicians regard their work as "geriatric" simply because they have a great many elderly patients by virtue of their work setting, the number of years they have been in practice, the age distribution of patients requiring their expertise, or their geographic location (103). It was estimated over a decade ago that 40 percent of the average internist's patients were 65 or older and that they took up about 60 percent of the internist's time (33). A more recent prediction is that medical school graduates will, at the peak of their careers, spend 75 percent of their time with patients who are 65 or older (27). Clearly, however, caring for elderly persons does not qualify one as a specialist in geriatrics. (By the same token, age 65 alone does not necessarily mean that a patient requires a physician with special geriatric expertise. Most authorities cite 75 as a more accurate criterion for the "geriatric population.")

Specialists in Critical Care Medicine and Nursing

The widespread development and application of modern life-sustaining technologies has caused and, in turn, has been assisted by the development of new specialties—most notably critical care medicine and critical care nursing—in a new health care setting, the intensive care unit (ICU). In the intensive care setting, physicians, nurses, and other health professionals work together closely, ideally as members of the *ICU team*. A National Institutes of Health consensus development conference characterized critical care as:

> a multidisciplinary and multiprofessional medical/nursing field concerned with patients who have sustained or are at risk of sustaining acute life-threatening single or multiple organ system failure due to disease or injury (115).

The Society of Critical Care Medicine has approximately 2,900 members. Almost 90 percent are physicians; the rest are mainly nurses and respiratory therapists (135). The primary specialty of most critical care physicians (also referred to as "intensivists") is either internal medicine, anesthesiology, surgery, or pediatrics. However, physicians from many other specialties (e.g., emergency medicine, neurology) and subspecialties (e.g., pulmonary medicine, cardiology, nephrology) are routinely involved in the care of critically ill elderly patients.

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[2] There has been considerable debate over whether geriatric medicine consists of a discrete body of knowledge and skills that warrants clinical or pedagogic organization as an independent specialty, whether it should be included in all adult medical specialties, or whether it should be a subspecialty of internal medicine, family practice, or both. This debate appears to be coming to a close with the recent decision by the American Board of Medical Specialties to authorize the American Board of Family Practice and the American Board of Internal Medicine to offer special geriatric certification within family practice and internal medicine. Geriatrics is not currently a formal (i.e., board-certifiable) specialty or subspecialty and OTA uses the terms "geriatrician" and "geriatric specialist" interchangeably (see "Credentials in Geriatric Medicine and Nursing," below).

Nurses who specialize in critical care provide nursing diagnoses and interventions in life-threatening illness. According to the American Association of Critical-Care Nurses (AACN), critical care nurses are challenged to provide "humanistic care in the high-technology world today and in the future" (4). Membership in the association, one indicator of the number of nurses working in critical care, is currently about 53,000 (44).

Under the umbrella of critical or intensive care, another level of specialization is pertinent to the provision of life-sustaining technologies. For example, critical care nurses may specialize in respiratory care, parenteral and enteral nutrition, or intravenous therapy. A very small number of critical care nurses have had training in gerontological nursing (127). In other health professions, where the work is not exclusively with critically ill patients, the same pattern exists. For instance, there are dietitians who specialize in critical care and social workers who specialize in nephrology.

In large teaching hospitals, it is estimated that approximately 35 percent of all ICU patients are at least 65 years old (149). Thus, most health care professionals involved in the implementation of life-sustaining technologies have considerable experience with elderly patients. As suggested above, however, exposure to elderly patients does not guarantee the special knowledge, attitudes, and skills that good geriatric care requires. There appears to be no educational or training program within either critical care medicine or nursing that focuses attention on elderly patients (44,69). The position of AACN is that:

> . . . the practice of critical care nursing is generic to any critically ill patient, regardless of the age of that patient and that knowledge of the lifespan processes affecting individuals is given in one's basic nursing education program (44).

Allied Health Professionals

In the provision of life-sustaining technologies, the roles of physicians and nurses are supplemented and complemented by allied health professionals who are responsible for specific, often highly technical tasks. The allied health professions most closely linked to resuscitation, mechanical ventilation, dialysis, and nutritional support are briefly described here. Life-sustaining antibiotic therapy is prescribed by a physician and administered by a registered nurse; in general, such therapy does not require personnel that are unique to this technology (see "Technology-Specific Credentials," below).

- In the hospital, resuscitation is usually performed by physicians or nurses who have been trained and certified in cardiopulmonary resuscitation (CPR). They may be assisted by *respiratory therapists* or by *paramedics* (see below).
- In the community, *emergency medical technicians (EMTs)* are usually the first health professionals to arrive at the scene of an accident or medical emergency. Both EMT-ambulance and the more highly trained EMT-paramedics provide basic life support to restore breathing, treat shock, control bleeding, etc. The EMT-paramedic may implement advanced life support technologies including administration of drugs and oxygen, insertion of an intravenous line, intubation of the lung, and operation of a defibrillator. All these and other treatments are performed under the supervision of a physician, with whom the EMT is in constant communication (76,81).
- *Respiratory therapists* and *respiratory therapy technicians* may administer mechanical ventilation, oxygen therapy, assist in CPR, and perform other less invasive treatments including chest physiotherapy. Other responsibilities include performing diagnostic tests and monitoring, as well as adjusting, sterilizing, and maintaining equipment.

  Respiratory therapists are more highly trained than respiratory therapy technicians and are generally given more responsibility (including research, teaching, and supervision of respiratory therapy technicians), but their actual duties vary greatly from one hospital to another (76,106). Both types of personnel work under the supervision of the chief of the respiratory service (a physician or respiratory therapist).

Respiratory therapy assistants have limited patient contact; their roles include cleaning and maintaining equipment, processing inventory, and other clerical duties (2).

- *Dialysis technicians*, working under the supervision of either medical or nursing personnel, function in one or more of four areas: direct patient care, research, administration, and equipment maintenance and repair (5).
- *Dietitians* have roles that may be primarily clinical, administrative, research, or teaching; they may work as staff of an institution, as consultants, or in the community (106). Specialists referred to as *nutritional support dietitians* or *dietitians in critical care* are skilled in the use of enteral and parenteral solutions, modular nutrients and foods. They collaborate with physicians, nurses, and pharmacists to assess nutritional status, design dietary treatment, and monitor its effectiveness. Under the guidance of a registered dietitian, *dietetic technicians* and *dietetic assistants* may also be involved in the care of patients receiving enteral nutrition (6,14).
- *Nutritional support pharmacists* are specialists who participate in the assessment and care of patients who may require nutritional support. In collaboration with other health professionals, the pharmacist's role includes ongoing assessment and planning, provision of care, monitoring and evaluating the patient's response. It is also the role of the pharmacist to prevent problems related to the interactions between nutrients and drugs a patient is receiving (15).
- The role of *medical social workers* is to help prevent or resolve social, psychological, and economic crises that may arise from an illness, the proposed treatment, or the environment. They may contribute to decisions about the use of life-sustaining technologies by providing other caregivers a composite picture of the patient within the context of his or her family, life-style, and community. They educate and provide emotional support to patients and family members, to help them understand the situation and options. Preceding a patient's discharge from a hospital, or in the event of death, medical social workers identify community services and make logistical arrangements (105,106). Some social workers, e.g., *nephrology social workers*, specialize in the care of particular groups of patients.

THE HISTORICAL CONTEXT OF GERIATRIC PRACTICE

The establishment of Medicare in 1965 helped focus public attention on the health care needs of the elderly, but predated almost all opportunities for health professions education and training in geriatrics or gerontology. A 1969 survey found that fewer than half the medical schools in the country (48 of the 99 schools then in operation) included in their curricula even a single course with any identifiable content related to aging (62). The Division of Gerontological Nursing within the American Nurses' Association had been established in 1961; advanced nurse training leading to certification as a geriatric nurse practitioner, however, did not become available until the 1970s. Programs to prepare allied health professionals in geriatrics and gerontology are much more recent than programs in medicine or nursing.

Largely because of Federal support, major progress has been made in expanding the educational and training opportunities in geriatrics and gerontology. However, very serious deficits remain in the level of geriatric expertise among health care professionals generally and in the number of individuals who have chosen to specialize in the care of the elderly.

In 1978, a study conducted by the Institute of Medicine found serious deficits in geriatrics education and training in medical schools as well as postdoctoral and continuing medical education (77). Only a few schools offered geriatrics as a separate subject, and almost no schools required it. A 1983 survey of geriatric education in medical schools documented considerable expansion of geriatric course offerings, but found that in 28 percent of the responding medical schools, geriatrics was still either elective or unavailable (21).

While some gerontological content is now included in most basic professional nurse training programs, only about 14 percent of these programs offer full courses in gerontological nursing (148). Until 1981, the geriatric track was an option within programs that were based on the core curriculum for adult nurse practitioners (52). Now, among approximately 200 nurse practitioner programs, about 40 have a primary focus in geriatrics and approximately 31 others have a gerontological component (148). Many of these programs, however, have as few as three or four trainees (155).

In the allied health professions, the extent of training opportunities is difficult to assess, in part because "allied health professions" includes so many different groups. Recognition of the need for attention to the elderly is evident in the American Dietetic Association's 1978 establishment of the Gerontological Nutrition Dietetic Practice Group and the American Society of Allied Health Professions' 1986 establishment of a National Task Force on Geriatric Care Education (134). Another indication of the developing interest in geriatrics among the allied health professions is that a Department of Health and Human Services (DHHS) forum on Personnel for Health Needs of the Elderly, held in October 1986, drew presentations by official representatives of respiratory care, social work, physicians assistants, occupational therapy, optometry, and others.

Federal Support for Geriatrics

Federal support of geriatric training began with early Veterans Administration (VA) programs and was greatly bolstered by the establishment of the National Institute on Aging (NIA) in 1974. Currently, geriatric education and training receives support from the VA and from several DHHS agencies (the Administration on Aging, National Institute on Mental Health, and the Health Resources and Services Administration) in addition to NIA. There is considerable range in the scope, focus, and financial commitment of these various agencies to geriatrics. In addition to the Federal Government, a number of State governments and private foundations have also demonstrated their interest and commitment to strengthening geriatric manpower. Some programs are designed to increase geriatric knowledge and skills among health professionals generally; others are designed to prepare leaders in geriatric teaching, research, and practice.

The largest Federal programs in geriatrics are the VA's Geriatric Research, Education and Clinical Centers (GRECCs) and the Health Resources and Services Administration's Geriatric Education Centers (GECs). These multidisciplinary training centers are important resources for both students and practicing health professionals. GECs increase the "presence" of geriatrics within academic institutions and their communities, and increase access to training and to trained caregivers, including some of the professionals involved in the delivery of life-sustaining technologies. Some of the GRECCs are focused on problems relevant to life-sustaining technologies. The GRECC in Little Rock and the one in St. Louis, for example, have been designated as "nutrition GRECCs."

In contrast, the rapid development of the medical specialties that are associated with critical care (cardiology, pulmonology, nephrology, oncology, and others) was facilitated by extensive Federal support of biomedical research during the 1960s and 1970s and by Medicare's support of hospital-based clinical training. However, there have been no Federal programs specifically earmarked for support of training in critical care medicine or critical care nursing.[3]

It is recognized within the Federal Government that, despite the commitment of funds, the clear progress, and a projected surplus in the total physician supply (145), the supply of health professionals with expertise in geriatrics remains very inadequate. In 1984, an NIA report cited continuing deficits in available education and training of physicians, nurses, and other professionals in geriatrics and gerontology (148). Specific steps to alleviate these deficits were recommended. A 1985 amendment (H.R. 2409) to the Public Health Service Act required the Secretary of Health and Human Services to conduct a study on the adequacy and availability of health personnel to care for America's elderly over the next four decades (143). The Secretary's report will be presented to Congress in mid-1987.

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[3] Training programs in critical care have had to compete for more general health professions education funds, for example, through Title VII (medical training) and VIII (nurse training) of the Public Health Service Act. Some observers believe that the recent designation of critical care medicine as a subspecialty will improve its ability to secure funding (69).

The shortage of qualified teachers is a serious problem, and it helps perpetuate the shortage of qualified practitioners. In nursing, "the inadequate preparation of faculty in gerontology" is cited as the "largest single problem in strengthening the gerontological content in basic schools of nursing" (148). The same was concluded about medicine in 1984 (148) and again in 1986 at an Institute of Medicine and NIA workshop, which concluded that the number of well-prepared medical faculty is far from adequate, and opportunities for would-be faculty to receive appropriate graduate training remain very limited. In 1985-86, there were 48 fellowship programs in geriatric medicine offering 176 positions (and 21 fellowship programs in geropsychiatry, offering 52 positions) (23).[1] In nursing and the allied health professions, training opportunities are even more limited.

Shortage of Geriatric Expertise

Caregivers who lack formal education and training in geriatrics are not necessarily unprepared to care for elderly patients. Nevertheless, there is ample evidence of a severe shortage of medical and nursing expertise relevant to the complex problems presented by many elderly patients. Disease and disability among the elderly are frequently misdiagnosed, mistreated, or simply written off as concomitants of normal aging. A condition that is aggressively treated in younger people may be mistakenly regarded as irreversible—or it may be perceived as a blessing.

Geriatric consultation units have reported finding many elderly hospitalized patients with potentially treatable conditions that had been either misdiagnosed or overlooked entirely (1,38,94). Some examples of inadequate knowledge and skills regarding elderly patients or ageist biases that are relevant to life-sustaining technologies are: caregivers' difficulty in assessing the decisionmaking capacity of some elderly patients; the assumption that elderly patients will not do well on dialysis or that elderly ventilator patients can never be cared for at home; or, alternatively, the belief that the same nutritional support formulas or drug dosages used for young adults are suitable for the old.

Because of geriatrics' late entry in academia there is a considerable need for continuing education programs in geriatrics. Such programs are the only way to reach the majority of health professionals whose formal education predated opportunities in geriatrics. In the last few years, medical schools, State and local medical societies, professional societies, and others have increasingly offered courses for practicing physicians and nurses. However, there are no mechanisms either to require participation in geriatric continuing education programs or to control the quality of the programs.

Advanced training in geriatrics seldom includes special attention to the care of the critically ill. Fellowship programs in geriatric medicine generally do not include training in ICUs, and certification in gerontological nursing does not require experience with the critically ill. As a result, some geriatric specialists might have unrealistic expectations about what critical care can accomplish and may seek admission to the ICU for elderly patients who cannot be helped there. Conversely, postgraduate medical and nursing training in critical care does not appear to include specific attention to aging (7). A certain amount of cross-training in geriatrics and critical care could improve communication among caregivers and, thus, lead to more appropriate treatment decisions on behalf of elderly patients.

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[1] Experience suggests this would result in about 65 graduates per year (23).

Shortage of Geriatric Specialists

Physicians

In addition to the need for geriatric expertise among primary care physicians, there is also a need for a certain number of specialists to serve as teachers, researchers, medical directors in nursing homes, and as consultants in complex cases (35). In a landmark study commissioned by NIA, researchers at the Rand Corp. developed estimates of the need for these geriatric specialists. By 1990, Rand estimated, there will be a need for approximately 8,000 full-time-equivalent (FTE) geriatricians providing patient care and 900 FTE academic geriatricians (82). Rand's projections were conservative in that they were targeted to the population aged 75 and older, assumed only a small increment in the quality of care, and did not include the large and crucial component of geropsychiatrists. Moreover, one author of the Rand report now points out that, when newer demographic projections are taken into account, the need for geriatric specialists is much higher than originally estimated (22). In sharp contrast to the estimates of need, unpublished data from the 1983 Physician Masterfile of the American Medical Association included only 1,833 physicians who identified geriatrics among their specialty fields (104). In March 1986, American Medical Association data included only 922 active physicians who identified geriatrics as their primary specialty (12).

A 1982 survey of physicians found that the estimated number who designated geriatrics as one of their specialties more than doubled between 1977 and 1982, from 715 to 1,618 nationally (103); since 1982, further annual increases have been documented (104). However, physicians tend to enter geriatrics relatively late (mean age 39) and spend, on average, only half their work week in geriatrics, factors that effectively reduce their contribution to the manpower supply. In 1982, there were approximately 10 percent of the number of FTE geriatric clinicians and 13 percent of the number of FTE researchers/teachers that Rand said would be needed in 1990 (103).

Nurses

Similarly, there is a severe shortage of nurses specializing in gerontology or geriatrics. A 1983 report by the Institute of Medicine concluded that registered nurses with graduate education prepared to administer the increasingly complex care demanded in some settings (e.g., the ICU), as well as nurses willing and trained to work with the elderly, especially in nursing homes, remain in short supply (as do nurses in rural areas and inner cities), while the general nurse shortage of the 1960s and 1970s has dissipated (78). Consistent with this conclusion, a 1984 DHHS report to Congress (148) identified a severe shortage of nurses adequately trained to care for the elderly or to teach in nursing schools. Compared with the estimated need for 2,450 gerontological nursing faculty, a 1980 survey by the Health Resources and Services Administration identified only 420 nurses with master's or doctoral degrees whose primary focus was geriatrics or gerontology (148).

Allied Health Professionals

Information regarding geriatric specialization among allied health professionals is unavailable. In view of the limited opportunities for training, however, the numbers of allied health professionals with geriatric expertise are certainly inadequate.

Barriers to Recruitment in Geriatrics

Efforts to attract health professions students to academic experiences in geriatrics and/or to geriatric careers have historically faced a variety of barriers. Low enrollment in elective courses in geriatrics and the shortage of applicants for geriatric fellowships (with the result that some positions go unfilled) are indicators that interest is still limited. In New York, geriatrics has been exempted from a State policy that excludes foreign medical graduates from postgraduate medical training (121). The ability of unlicensed physicians to secure work in some nursing homes and the shortage of nurses for nursing home work (78) are further indications that competition for jobs in geriatrics remains low.

One reason is *ageism*, the general societal prejudice against the elderly (33,35). The irreversibility and deterioration associated with many chronic conditions and the poor prognosis of many elderly patients with acute illness are powerful images, particularly when contrasted to the physician's self image as a healer. Working with elderly patients is said to evoke caregivers' fears of their own old age, their own mortality and their relationships with elderly family members as well as fears of their fallibility (45,96). Compared with care of the elderly in general, care focused on the critically and terminally ill elderly may intensify these fears. Furthermore, the negative attitudes and stereotypes frequently associated with old people appear also to adhere to the individuals who provide their health care (60). Geriatricians have been stereotyped as sympathetic but underskilled physicians who drifted into geriatrics as their patients (and they themselves) aged. Nurses who work in nursing homes have been widely regarded as inexperienced and undereducated (142).

Another reason for disinterest in geriatrics has been the relatively low remunerative potential. It is no secret that "older patients are somewhat of a losing proposition if they are considered simply in a business sense" (92). When first established, Medicare and Medicaid appeared to some health professionals to create a new market for their services. By providing reimbursement for the care of elderly (and other) patients, these programs drew attention to geriatrics and stimulated interest both in caring for elderly persons and in working in nursing homes. More recently, however, the limited reimbursement available under these programs has been cited as a disincentive to geriatric work (54,92,131). Although coverage and reimbursement levels under Medicare Part B provide financial incentives to physicians in hospital-based, procedure-oriented specialties, the relatively low reimbursement available for the more "cognitive" specialties is an economic disincentive for primary care specialties in general and geriatrics in particular. There is, for example, no allowance in Medicare reimbursement for patients who require excessive amounts of a physician's time, whether for extended office visits, frequent phone consultations, or travel to a nursing home.

For registered nurses who complete advanced training in geriatrics or gerontology, Federal reimbursement policy may actually restrict employment opportunities. The services of geriatric nurse practitioners are directly reimbursable by Medicare, but only when the geriatric nurse practitioner is supervised onsite by a licensed physician. In hospitals, this requirement is easily met. In most nursing homes, however, this requirement makes reimbursement difficult to obtain. As a result, highly trained geriatric nurse practitioners are too expensive for most nursing homes to hire. Similarly, Medicaid's restricted payments for skilled nursing personnel appear to leave most nursing homes with a choice of paying high salaries to a few highly trained nurses or paying low salaries to a large number of unskilled aides (78).

Another source of negativism regarding geriatrics—of particular relevance to this discussion—is the fascination of American medicine with technology and the view that geriatrics is a "low-tech" field, concerned primarily with the management of patients with chronic, irremediable problems. Nursing homes, where most geriatric work is assumed (wrongly) to occur, have been dubbed a "no tech" environment (101). Under this view, the application of high-technology critical care medicine and geriatrics might seem antithetical. Persistence of the low-tech image contributes to the belief that geriatrics is an unexciting, unchallenging field.

Failure to see the relevance of medical technology in general and critical care technologies in particular to geriatric practice could be attributed to the attitude that the potential life-sustaining benefits of complex, expensive medical care are "wasted" on the old. Or, it could be attributed to the belief that geriatricians are exclusively concerned with chronic illness and that patients in their care escape the acute life-threatening episodes that occur in other age groups.

In comparing geriatrics with other medical specialties, the issue may not be how much or how "high" the technology, but qualitative differences in the technologies that are relevant. In geriatrics, tools for functional assessment and differential diagnosis, rather than technological hardware, are the mainstay. However, it is necessary that the geriatrician know enough about potential life-sustaining technologies and their efficacy to contribute to decisions about their use for individual patients. This includes:

> . . . competent familiarity with the capabilities of the latest in medical technology, a discerning sense of judgment about when and when not to use such interventions, and the courage and energy to take seriously the social role of advocate for the patient (41).

EDUCATION AND TRAINING NEEDS: SELECTED CONTENT AREAS

The knowledge applicable to the care of elderly patients who are candidates for or already receiving life-sustaining technologies may be considered in two very broad categories: general knowledge about caring for elderly patients who are critically ill, terminally ill, or severely debilitated and knowledge that is linked to the use of specific technologies. The following selective review identifies subjects that may have particular importance in the assessment and care of life-threatened elderly patients.

Technology-Independent Content

Some essential knowledge is not linked to any life-sustaining technology in particular but is basic to decisions about the use of all life-sustaining technologies for elderly persons. Knowledge of this sort includes clinical factors that distinguish elderly patients from younger ones and humanitarian and social perspectives that recognize the uniqueness and autonomy of each elderly patient.

Clinical Geriatrics

Health professionals caring for severely ill elderly patients must be knowledgeable about age-related physiological factors, and their interactions. To make correct diagnoses and treatment recommendations for elderly patients, caregivers must know that certain illnesses have unusual presentations or progressions in elderly patients. The presentation of some illnesses in elderly patients may be characterized by specific signs and symptoms that differ from the classic presentation of the same illness in younger adults, or frequently, by nonspecific signs and symptoms that do not clearly indicate the affected organ system. Elderly patients having heart attacks, for example, do not always experience chest pain. Instead, they may have other signs and symptoms such as sudden loss of consciousness, confusion, or sudden onset of heart failure. Pneumonia may be present without any of the classic signs (e.g., fever, elevated white blood cell count); instead, there may be only nonspecific manifestations such as confusion, lethargy, or weakness (16,129,130).

Caregivers must recognize that elderly patients are at higher risk than younger patients for developing complications of illness and complications of treatments. Because complications, especially those related to drug interactions, drug toxicity, nosocomial infections, and malnutrition, may be severe and potentially fatal, expertise in their prevention and treatment is important. Even while a patient is in the midst of an acute problem that is immediately life-threatening (e.g., respiratory insufficiency) and is treated with some sophisticated technology (e.g., mechanical ventilation), the patient's caregivers must also be concerned with prevention of iatrogenic complications (7).

Certain psychological problems that are more frequent with advanced age become particularly significant when a patient's physiological status is already compromised. Impaired mental functioning (whether due to cognitive or affective disorders) may have serious implications for a patient's ability to participate in treatment decisions and may diminish the efficacy of some life-sustaining treatments. This heightens the importance of caregivers' knowledge about prevention, diagnosis, and possible treatment of psychological problems.

It is essential that caregivers be able to fairly assess each patient's capacity to understand proposed treatment options and to participate in treatment decisions. They must be aware that a patient's mental state may be influenced by a number of factors such as drug toxicity or infection, that the condition may be reversible, and that cognitive impairment can never be dismissed as an aspect of "aging" or "senility."

Effective treatment of depression or confusion may facilitate an elderly patient's cooperation with life-sustaining treatments and thus improve their efficacy. It is far easier and safer to administer treatments such as dialysis or mechanical ventilation to a cooperative, lucid patient than to a disoriented, combative one who continually attempts to remove intravenous, nasogastric, or tracheostomy tubes. Also, patients with improved mental functioning are better able to communicate with caregivers about symptoms they may experience and, thereby, can assist in early detection of complications.

When critically ill or diagnosed as terminally ill, patients are at heightened risk for developing new cognitive and affective problems as well as exacerbations of existing conditions. Hospitalization, especially in an ICU, is itself a risk factor for developing certain types of cognitive dysfunction. Psychiatrists and others have described a phenomenon termed "ICU psychosis," referring to a fairly common occurrence wherein the stress of being an ICU patient induces a temporary psychosis akin to "combat fatigue" in soldiers (70,83,85,136). Physicians must recognize that elderly persons may have less reserve to tolerate the stress engendered by illness and ICU admission and thus may be more likely to develop this iatrogenic condition.

For nurses and certain allied health personnel who typically spend more time with patients than do physicians, psychological expertise is also important. Such expertise can facilitate earlier detection of problems; it can also enable caregivers to exert more positive influence over the patient's subjective experience and to provide patients more help in coping with stress (61,140). Over the last decade, nurses have done much to define and systematize psychological expertise. They have developed nursing diagnostic categories to identify and classify many types of patient problems related to coping and stress, and they have developed nursing management techniques to assist patients with psychological problems (86,87).

Humanities and Human Values

It is increasingly recognized that many clinical problems cannot be understood solely in terms of the biomedical and technical aspects that were the foci of traditional medical education. The introduction of the social and behavioral sciences and, in general, broader concern for humanistic issues represents significant change both in medical education and in the education of other health professions that sometimes take their lead from medicine. Medical school admissions criteria (116), curricula, and teaching methods are being reevaluated (11,20) and, in some cases, revamped in reaction to such trends as ethical issues raised by improved technology, the aging of the population, more patients who wish to be active in treatment decisions, pressure to contain or reduce costs, and the threat of malpractice suits. The Standards for Accreditation of Medical Education Programs Leading to the M.D. Degree, as ratified by the American Medical Association's Liaison Committee on Medical Education in March 1985, state:

> The curriculum cannot be all-encompassing. However, . . . there should be presentation of material on medical ethics and human values. . . . All instruction should stress the need for students to be concerned with the total medical needs of their patients and the effect of social and cultural circumstances on their health. The students must be encouraged to develop and employ scrupulous ethical principles in caring for patients, in relating to patients' families, and to others involved in the care of the patients (13).[5]

A survey of medical schools conducted in 1980 to 1981 found that nearly all medical schools had introduced courses in "humanities" or "human values." What this means in terms of either content or commitment varies greatly from institution to institution. The range is from a 2-year postdoctoral fellowship in Clinical Medical Ethics,[6] and full-length required courses, to elective mini-courses and informal methods such as "ethics rounds." This instruction may go on in the preclinical years of medical school or during the clinical years and subsequent training (especially during primary care residencies). Formal courses in the humanities range in focus from philosophical ethics, clinical ethics, and death and dying; to his-

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[5] Similarly, the National League for Nursing Standards of Accreditation for undergraduate and graduate programs in Schools of Nursing require evidence of ethics in the curriculum (113).

[6] In 1986, the University of Chicago's medical school instituted the first such program.

[illegible] art, literature, interviewing techniques, and human sexuality (120).

The impact of such curricular innovations on medical practice is difficult to evaluate. Some advocates of humanities education say that its timing within the full medical school program and the setting in which teaching occurs may have substantial effect on its value. Others are skeptical about any approach that simply adds formal instruction in humanities and ethics to a system in which professional selection and socialization patterns continue to reinforce the status quo. At a time when many believe the need for education in ethics and human values is greater than ever, unstable funding for these programs, much of which has come from the National Endowment for the Humanities and private foundations, threatens the survival of many (40).

Death and Dying

Another new content area in medical education important for caregivers to the critically and terminally ill elderly is "death education." Courses in "death and dying" or "caring for the terminally ill" (like broader humanities courses) have grown out of recognition of the need for a more humanized approach to caregiving. They aim to counterbalance the technical training of health professionals.

Death is viewed by many physicians not merely as the enemy of the patient, but as the "dragon" in their "never-ending crusade to protect life" (98), and as a symbol of their own personal defeat. One physician's editorial about his habit of attending his patients' funerals, therefore, attracted national attention (79). More typical is the avoidance behavior depicted in the story in box 10-A.

It is hard to imagine that a physician who cannot accept the death of a patient could help patients and families consider a life-sustaining technology or deal with the dying process. Physicians' personal and professional difficulty in dealing with the death of their patients underscores the need for education in death and dying.

A 1980 survey of all medical schools in the country found that 80 percent of responding schools offered some formal death education, but that very few of these courses existed before the early 1970s. Most schools offered only an occasional lecture or "mini" course; the number of full-term

Box 10-A.—Not on My Shift

She was a 72-year-old woman who had been recently transferred by helicopter from a smaller hospital. She had started bleeding from a duodenal ulcer and was in serious condition. The attending surgeon and medical consultant both agreed to try aggressive medical management because of the risks of surgery. But she continued to bleed despite treatment and was taken to surgery that evening.

It was a Saturday night, and I was getting a report from the surgical resident who had been on call the previous shift. "We had quite a time with your patient last night," he said. "She survived the operation, but I think she'll probably die sometime today."

"Not on my shift," I blurted out without thinking.

As I went through my surgical rotation in medical school, and now in residency, this situation had come up many times. There was always one patient on a service who was close to death. The residents did everything possible not to let the patient die on their night on call. It was inevitable that the patient would die, but to let that person die on your shift was a sign of failure.

My night on call started as usual: an admission from the emergency room to rule out appendicitis, a traffic accident victim with only superficial wounds, a few calls to the floor. Then I was called to the intensive care unit. My patient's blood pressure was dropping, and her urine output was low. From that point, I was in and out of the ICU all night: increasing her fluids, transfusing blood, adding a dopamine drip, inserting a catheter and an arterial line, giving albumin, putting her on a ventilator; it went on and on.

Finally, it was 7 a.m., time for me to give the report to the next surgical resident. I described the evening's work with my patient and said that she was in serious condition, that I thought she would probably die during the day.

The oncoming surgical resident flashed back, "Not on my shift!"

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courses was just 16. At most medical schools, at least half of all students take the death and dying offering (49). A sample medical school course (University of Washington) addresses the following topics: personal attitudes toward death, patient and family reactions to dying, role of the physician, role of the clergy, children and death, medical ethics in terminal illness, *aging and death*, grief and mourning, symptom management, and interdisciplinary care of terminal illness (65).

The important role nurses play in the care of life-threatened and dying patients has also been recognized, as seen by inclusion of death education in the nursing curriculum. "Nurses have the potential to enhance understanding of death with patients or to create even more problems for patients" (110). A survey of schools of nursing found that by the late 1970s, 45 percent of the responding schools offered some instruction related to death and dying (141). An elective course in "dying and bereavement" at the University of Wisconsin-Milwaukee nursing school includes these issues: dealing with death, ethical and legal issues, postdeath activities, grief and survivorship, and community resources (139). Another example is a 2-day training program for nursing home nurses that aims to increase their knowledge about death and dying and stimulate empathetic responses (110).

A curriculum on death and dying has also been proposed for allied health (50). The relevance of such curriculum has been discussed for physical therapists, occupational therapists, and some other allied health professionals.

Almost no training is available now to help caregivers deal with *their own* feelings of loss, grief, and self-doubt. They are left on their own to develop coping strategies (34), which at times are detrimental to their own well-being or may affect their professional performance. Physicians' responses to patients' deaths may bring physiological or psychological symptoms that can lead to such negative behaviors as minimizing contact with the patient or family, blaming others, and turning to alcohol or drugs (114). The ability of caregivers to resolve their personal feelings requires the kind of understanding that death education may help to provide.

Health Law

Courses in medical law and public policy also have been added recently to the health professions curricula. Topics such as informed consent and patient autonomy are often included. However, law courses for health professionals often direct little attention to the substance and analytical approach of the law and give scant attention to physicians' attitudes toward the law and toward legal risk. One result is that "physicians may unrealistically expect more certainty from the law than they do from medical science" (84).

For physicians currently in practice, the main source of information about the law is advice from hospital lawyers and risk managers. Other sources include articles in medical journals and legal advice columns, and "throw-away" journals that frequently contain articles highlighting concerns about malpractice. Although these are potentially valuable teachers, each has been found to contain occasional errors or biases that misinform and mislead (84). Other problems have resulted because "many lawyers advising . . . hospitals . . . lack experience and training in health law and have little familiarity with either medical practice or hospital procedures" (17).

A potentially important source of information about the law is continuing education; currently, however, few continuing education courses devote much attention to legal aspects of medicine. One exception is the American Heart Association's (AHA) course to recertify physicians in CPR. The handbook for this course includes advice concerning decisions to resuscitate and when resuscitation efforts should be terminated"[7] (84).

The lay press and media also provide health professionals information about legal and ethical matters. However, news coverage provides snapshots rather than a developmental view of events. For example, there was much publicity surrounding the murder indictment of two California physicians who discontinued a patient's life-sustaining treatment. But, the fact that the doctors were eventually exonerated received little attention. One result was a subsequent case involving physicians who refused to disconnect a ventilator from a brain-dead patient, even though this procedure was expressly permitted by California law (84).

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[7] However, some observers believe that the AHA recommendations are overly conservative and so based on concerns about litigation that they are at odds with actual clinical practice. Discrepancies between legal advice and clinical practice may intensify physician uncertainty and cynicism about the law (84).

Decision Analysis

The ability to synthesize and interpret the immense amount of information pertinent to complex clinical decisions and to select from among the many potential treatments is extremely difficult, and it is made ever more difficult as the knowledge base grows. New techniques collectively referred to as "decision analysis," "medical decisionmaking," or "clinical decisionmaking" are being developed to help systematize decisionmaking processes and, in particular, to treat objectively the persistent element of uncertainty (42,150). Most proponents of these methods do not claim that this kind of analysis can solve difficult clinical decisions, but rather that physicians who understand and appreciate statistical probability, uncertainty, risk, and error can learn to approach clinical decisions with greater clarity, objectivity, and prognostic accuracy.

Decision analysis methods are quantitative; they may use computers (as well as computerized databases) and sophisticated mathematics, but also accommodate issues of ethical values and cost.[*] The emphasis is on learning to structure complex decision problems, evaluate data, and develop strategies for reaching diagnostic or treatment decisions. "Learning to think scientifically often involves replacing common-sense views with more rigorous analysis" (55). Theoretically, at least, a physician applying decision analysis methods would be more careful than to think, "If I put this patient on a mechanical ventilator, he will probably die anyway." Rather, a specific statistical probability would be computed, and its meaning in relation to an individual patient understood. However, most proponents of these mathematical models insist they are not yet ready for direct clinical application—and many believe they never will substitute for a physician's clinical judgment. The methods are not intended to be applied in cookbook fashion that could permit physicians to "stumble into counter-intuitive traps" (109).

Since the late 1970s, research and training in decision analysis methods have all expanded rapidly. Courses have been introduced into the curricula of some medical schools, postgraduate training, and continuing medical education. At this early point, the extent and effect on patient care remain impossible to evaluate because what is taught in different institutions varies greatly and because much of this instruction is informal (56).

Technology-Specific Content

Much of the essential expertise associated with the delivery of life-sustaining technologies to the elderly is specific to the particular technology being used. Physicians must know the indications and contraindications for the available technologies so that they may offer appropriate treatment; they must also be able to recognize and treat complications. Nurses and other personnel must know how to apply the technology and assess patient response. Although the basic principles of technology-specific expertise are the same regardless of the patient's age, the application of these principles is often more difficult with elderly patients than with other adults because of their more complex patterns of illness. The presence of multiple diseases, including mental disorders, makes the delivery of effective overall treatment an elusive goal if personnel lack the knowledge that permits anticipation, recognition, and response to the special characteristics of many elderly patients.

For example, effective use of dialysis for elderly patients requires knowledge of how certain coexisting chronic diseases may affect this treatment. Vigorous hemodialysis, desirable because of increased efficiency and shorter treatment times, does not seem to be tolerated well by patients with impaired cardiovascular function, who require gentler treatments over longer periods of time. The use of large fluid volumes for peritoneal dialysis (desirable because of increased efficiency) is associated with further compromise of lung function in dialysis patients who also have chronic obstructive pulmonary disease (COPD). And dialysis patients with diabetes may need to have their insulin dosages adjusted; in fact, dosages of many common drugs must be modified for dialysis patients (46,100). Another example of technology-specific expertise is that needed to treat a COPD patient on a ventilator who requires nutritional support. To prevent a buildup of carbon dioxide in the bloodstream, which would exacerbate the patient's respiratory condition, the diet should avoid excess glucose (7).

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[*] A survey of members of the Society for Medical Decision Making found consensus that the following topics were essential for inclusion in introductory decision analysis courses for physicians: Bayes' theorem, decision trees, 2 x 2 tables, sensitivity and specificity, utility, and ROC ("receiver operating characteristics") analysis (57).

Technology-specific information is very complex and in some fields technological development is very rapid (see app. C. "Future Developments in Life-Sustaining Technologies"). It cannot be assumed that all caregivers know what they should, especially when the technological intervention is for an elderly patient. Besides the limitations of some individual caregivers, there are serious limits to the current knowledge base. Dialysis works, but experts do not understand why (see ch. 7). Caregivers may know well how to perform cardiopulmonary resuscitation and how to administer mechanical ventilation, but the knowledge base does not permit accurate prediction of the outcome in individual cases.

INTERDISCIPLINARY COLLABORATION

Competent clinical decisionmaking regarding the use of life-sustaining technologies frequently requires the collective expertise of many professions and specialties. Assuming that all the necessary subjects have been mastered, the remaining challenge is to bring this expertise together on behalf of a particular patient. The mechanism can be formal, as in the case of a "nutrition support team" or an "infection control team," or informal, but it always requires combinations of resources (including time) and skills. Effective combinations are difficult to establish, but without them, interdisciplinary care may be disjointed and inefficient rather than coordinated and creative.

Conflicting Perspectives and Goals

Good clinical decisionmaking involves setting treatment goals that are appropriate, realistic, and acceptable to the key parties involved. Depending on their particular profession or specialty, caregivers may have divergent frames of reference and sometimes different treatment goals that can lead to different assessments of the patient and different evaluations of the treatment options (151). One component of decisionmaking skill, therefore, is the ability to understand and appreciate all pertinent perspectives and, sometimes, to resolve conflicts among the various participants in the decisionmaking process. An especially difficult type of conflict would be a conflict between a physician (or caregiving team) and a patient (or the patient's surrogate). Other conflicts might arise when a physician or other caregiver is given "orders" to administer a treatment he or she believes is inappropriate. This is frequently the case when, for example, a resident is expected to carry out decisions made by the attending physician (154). Traditionally, nurses carried out physicians' orders without being involved in the decision. Increasingly, nurses seek more responsibility and the role of patient advocate, arguing that they may know better than physicians what patients want or what is best for patients (112). Also, the changing legal climate in which nonphysicians are increasingly held accountable compels nurses and others to question orders with which they disagree (44). Disagreements among caregivers may indicate that the patient is at the mercy of a poorly reasoned decision. At best, such conflicts are bad for caregivers' morale.

Medical Perspective

> . . . where the physician's work does not afford (at least in some symbolic sense) the possibility of saving a life or restoring health through skillful practice or losing them through ineptness, the physician lacks some of the essence of physicianhood (24).

Despite significant changes in medical schools and in the social environment since the quote above was published in 1961, the comment still reflects medical culture today. The medical model (which is the paradigm for most health education) sets up physician and patient as doer and receiver;

the physician has the responsibility to *do something* and the patient has the expectation that something will be done (137). The traits, habits, and mental sets characteristically nurtured by medical education perpetuate a perspective that tends to "medicalize" problems and view all problems, including death, as *treatable*.

> . . . death is construed as a biosystem going awry. The fatal illness is out of the patient's control and is operating as a tangible process, which becomes the target of treatment. In result, death becomes separate from the person who is dying. This human condition is inadvertently taken out of the realm of social meaning and put in a framework of normal versus pathological functioning. Here, death becomes viewed as a chronic resistance to life and is logically met with increased technological management (137).

In the case of patients who are critically or terminally ill, "physicians may adopt a hostile stance by retreating to technology" (114).

> I bent every effort to make sure that at the moment of death my patient had a normal white count, hemoglobin, sodium, potassium, chloride, carbon dioxide, and in fact to make sure that everything I could measure was normal. Only in that way could I convince myself that I had tried, that I had done enough. My patients, when they died, were the least sick dead patients one could imagine. This was really a refusal to face the death of a patient and a retreat to scientism, to technology, and was a means of convincing myself that I was performing important work in preventing death. It convinced me, against the facts, that I retained control (152).

Critical Care.—Critical and intensive care medicine exemplify the traditional goals of medicine, i.e., the cure of acute illness and the prolongation of life. The treatments of choice are generally treatments associated with the best case-fatality rates or other measure of longevity. Critical or intensive care personnel routinely use sophisticated technology and equipment to diagnose, monitor, and maintain function in a patient's acutely failing organ systems. They support organ function and maintain equilibrium during life-threatening events to give the patient's own recuperative abilities or definitive medical therapy an opportunity to act.

The exigencies and narrowly circumscribed goals of critical care medicine may distort the perspective of physicians during the decisionmaking process. Observers have alluded to the potential for ICU patients to be viewed as biological systems to which technologies may be applied. One intensivist has commented:

> Much of current medical practice operates tangentially to the goal of a happy and productive life. . . . Measurements and monitoring are frequently pursued as ends in themselves. Patients are transformed into physiological preparations as the norm of practice (128).

If the principal goal of critical care medicine is to maintain biological function, then the decisionmaking process may be reduced to a determination of whether technological intervention can improve or stabilize the parameters of organ function. The database selected for decisionmaking will consist of information related to this determination and may omit consideration of overall probability of survival, return of function, or quality of life. Technologies may be applied because they are available and not because they will improve outcome.

Typically, critical care is provided within an ICU, a stressful environment where time is always a factor, decisions are always important, many patients are too ill to participate in decisionmaking, and where nurses have a particularly important role. ICU physicians and staff treat the urgent, acute, and often complex problems of critically ill patients; this causes their patterns of practice to differ from those of their counterparts working on a general medical or surgical ward or in an outpatient facility. The NIH Consensus Report on Critical Care discussed this distinction with respect to nursing care:

> Nursing care in the ICU has an emphasis opposite from such care on general services. The effectiveness of the ICU nurse is his/her knowledge of all the details necessary to care for one or two patients while the effectiveness of the general service nurse rests upon his or her ability to direct care delivery by others to numerous patients (115).

The potential benefit from this type of specialization and division of labor is that caregivers may be able to use life-sustaining technologies more skillfully and treat acute illnesses more effectively and efficiently. Physicians who spend a great deal of time in the ICU may have a better understanding of both patients' experience in the ICU and the potential outcomes of intensive care (26). The potential risk is that the narrow approach that underlies this style of practice may adversely affect the decisionmaking processes of ICU personnel by distorting their perspective on the patient, that is, by causing them to look primarily at the patient's acute illnesses in terms of potential reversibility and not at the patient's overall condition in terms of potential function and quality of life (7).

Geriatrics.—Because chronic illness and physiological decline cannot be cured and will remain when an acute situation is resolved, geriatricians have argued that traditional medical goals are not appropriate for their patients. Geriatricians stress that when the eradication of illness is not possible, improvement of function and quality of life (as perceived by the patient) should be the guiding principles (67,75,123,124,129).

Familiarity with chronic illness may make geriatricians particularly aware of the fact that life-sustaining technologies sometimes increase the average prevalence and duration of morbidity. Antibiotics, ventilators, dialysis, nutritional support, and other life-sustaining technologies permit many patients to survive acute episodes, but survival is not always accompanied by improved functioning and quality of life. A patient with previously asymptomatic atherosclerosis may, as a result of intensive resuscitative efforts, survive what otherwise would have been a fatal heart attack; but he or she may suffer from chronic sequelae such as congestive heart failure and may live long enough to develop other complications related to atherosclerosis, such as a stroke (7).

Although there are no systematic data regarding either how geriatricians make treatment decisions or the particular decisions they make, it is reasonable to expect that they (and primary care physicians in general) would tend to behave differently than physicians who specialize in critical care. In particular, one might expect that geriatricians would be more likely to make decisions aimed at improving outcome in terms of function and quality of life, as opposed to mere survival. Because acceptable levels of functioning and quality of life are highly personal and subjective judgments, decisions based on these goals require that physicians be especially sensitive to and respectful of patients' assessments of their current or expected future condition and their wishes regarding treatment.

Some people believe that, as primary care physicians, geriatricians might potentially improve decisionmaking about admission to the ICU; or, as consultants to other physicians, might improve care within the ICU. A geriatrician might be able to provide a more complete database for decisionmaking; a geriatrician might also be more skilled than other physicians at recognizing and interpreting unusual clinical presentations and more experienced in the evaluation and management of cognitive and affective changes frequently seen in elderly patients. As primary care physicians, geriatricians would probably be better acquainted with patient value systems and personal preferences than intensivists who see patients for the first time in the ICU (7).

Nursing Perspective

To a large extent, nurses use their skills to carry out medical treatment prescribed by physicians. However, nurses argue, there is a distinct "nursing database" that informs nurses' perspective on a patient and that is essential to good care (66, 86,87). This database is comprised of information about the patient's physical signs and symptoms; physical, cognitive, and emotional functioning; and self-care abilities.

Functional assessment is a central component in many nursing diagnostic categories: among the nursing diagnoses approved by the National Conference on Classification of Nursing Diagnoses, for example, are activity intolerance, dysfunctional grieving, and impaired mobility (66,86,87,117). These diagnostic categories are used to identify problems that are amenable to nursing management. For example, nurses plan and implement interventions to alleviate certain types of psychological and physical discomfort and dysfunction and to prevent iatrogenic complications. In the acute or intensive care setting, nurses may independently institute measures to help patients feed themselves or to alleviate confusion by regularly orienting them to time, place, and person.

In the critical care setting, nurses with geriatric experience and training may be better able than other nurses to fully address functional and psychological problems in elderly patients. Some geriatric assessment units that employ physicians and nurses with geriatric experience to treat patients in acute care hospital wards have been able to improve the functional status of certain patients at discharge; as a consequence, some of these patients have not had to be discharged to other institutional settings. Nurses with geriatric expertise might also be able to contribute to improved outcomes in the intensive care setting (7).

Patient Goals

In many cases, patients have the same goals as physicians and willingly consent to therapy designed to achieve these shared ends; some patients even prefer to defer to their physician and allow him or her to make decisions in their best interest. Occasionally, however, the patient and physician disagree as to what is in the patient's best interest. Under the informed consent doctrine (see ch. 3), the patient's opinion is definitive in such cases.

The integration of principles of patient autonomy into the clinical decisionmaking process has not been fully accepted by the medical profession. Some physician authors have argued against patient participation in clinical decisionmaking, claiming that patients lack the experience and professional knowledge needed for making informed treatment decisions, and that it is unethical for physicians to allow patients to make "irrational" choices (i.e., choices different from those obtained using solely medical criteria) (18,19,48, 95). Some studies have indicated that decisions about treatment often reflect physician authority rather than patient wishes, and that physicians do not always consider patient wishes when selecting treatment (18,25,95). Because emphasis on function and quality of life are basic elements of geriatric training, health professionals with this approach may be better able to promote patient autonomy and patient satisfaction than physicians with other orientations (7).

Effective Teamwork

The various professionals who are involved in the care of a particular patient may be an ad hoc assemblage of individuals or they may be organized into a true health care team striving for comprehensive, appropriate, and coordinated care. When teams function properly, they can have many beneficial effects on patient care. Treatment selection decisions can be based on a more comprehensive database than might otherwise be possible. Treatment plans of physicians, nurses, and allied health personnel may be coordinated to ensure that all necessary treatments are delivered and that caregivers do not duplicate each other's efforts or work at cross-purposes. A recent study of more than 5,000 patients in 13 hospitals found that interaction and communication between physicians and nurses in the ICU were related to significantly reduced mortality (88).

Health care teams have no uniform composition or structure. The numbers and mix of caregivers participating in the delivery of any technology varies from one setting to another and, to a considerable extent, within settings of the same type (74). Further, the specific roles, responsibilities, and relationships of various professionals is different in different institutions. In practice, "team care" has often been invoked in instances where "many hands" were necessary. There has been "a lot of lip service given to the interdisciplinary approach," but the fact that physicians and nurses are working together does not necessarily mean that they constitute a real team (36).

Health care teams may have either a hierarchical or a "collegial" structure. Typically, a physician is the team leader. In part, this reflects the physician's traditional status within the health care system. Also, many physicians are reluctant to delegate and share responsibility because they ultimately bear major legal responsibility for the patient's care. Particularly in geriatrics, according to the Director of NIA, a collegial team is much preferred to a hierarchical one (153). The leader of a collegial team is "the first among equals."

Most health care teams, whether focused on geriatrics or critical care, make use of interdisciplinary assessments. When a new patient is referred to the team, each member examines and assesses the patient with respect to his or her particular field of expertise. Initial assessments are generally followed by treatment planning conferences at which the team attempts to reach a consensus regarding what treatments and interventions are most appropriate for the patient. The benefits of this approach for some patients have been demonstrated. In one study of elderly patients in a VA hospital, patients who were randomly assigned to the geriatric assessment unit subsequently had lower rates of mortality and of admission to nursing homes than the control group (132).

Each member of an interdisciplinary health care team can provide valuable information for determining what treatment will be offered to patients. Some of this information will be derived from the team member's technology-specific expertise. Other information will be derived from technology-independent expertise.

No systematic evaluations of the roles that nonphysicians play in treatment decisions have been conducted; narrative accounts of team conferences indicate that nonphysician professionals are present at decisionmaking conferences but do not describe the nature or extent of their contribution. Since physicians bear legal and professional responsibility for most of the decisions that are made, it is likely that they remain the controlling influence; however, other members of the team can participate in decisions regarding the selection and administration of life-sustaining technologies and even make certain types of decisions independently.

In addition to benefiting the patient, an effective team is valuable as an educational milieu for its members and is said to contribute to their morale (71). Critical care and geriatric specialists, psychiatrists, neurologists, and pulmonary specialists, nurses, dietitians, social workers, and others can all share their expertise and experience and support each other through difficult intellectual and ethical questions. Interdisciplinary team conferences can also be used as a method for training professionals to work in a team.

The potential pitfall of team care is that teams can be inefficient. In medical emergencies, a team may provide care (e.g., crash team), but there is no time for team assessment or decisionmaking. More generally, if the contribution of each participant is not clear, team planning conferences may become bogged down with the presentation of redundant information. Teams that do not establish clear lines of decisionmaking authority and attempt to make decisions by consensus may have difficulty making decisions. Teams with a large number of members or poorly defined member roles are particularly susceptible to these problems (133).

> It has become almost a watch word of GAUs [Geriatric Assessment Units] to talk about team care, but less has been said about the size and interdisciplinary composition of the core team. Teams may be very expensive and potentially inefficient. The solution appears to lie in using as small a core team as possible and mobilizing a variety of adjunctive specialists when appropriate (133).

Despite general agreement that teamwork is essential to good geriatric care (and claims that teamwork is one of the distinguishing features of geriatrics), training in team care has been inadequate. The importance of such training has been stressed by academic geriatricians who point out that acting as a collaborator (instead of "the boss") is not a role that comes easy for many physicians; it is something they must be taught to do (37). Lack of training in team care has had the result that the way teams frequently work is like "Who's in charge?" and "What's the mission?" (97).

THE IMPACT OF FEDERAL PAYMENT POLICIES ON THE EMPLOYMENT AND TRAINING OF HEALTH PROFESSIONALS

General efforts to contain health care costs and recent changes in Medicare's hospital payment policies were described in chapter 2. So far, there are only piecemeal data and anecdotes to describe how these changes have affected the use of life-sustaining technologies or the supply and training of health professionals.[9] The changes that are apparent suggest the powerful ability of the Federal Government to influence through reimbursement policy—intentionally or not—where and by whom life-sustaining technologies will be delivered as well as opportunities for related clinical training.

Employment Patterns and Personnel Needs

Hospitals

Data from the American Hospital Association's annual surveys document sharp reductions in total hospital employment from 1982 to 1985 (9) along with even sharper declines in hospital occupancy rates[10] (146). Overall, the number of full-time-equivalent health workers employed in hospitals (over 3.8 million in 1982) declined by 1 percent from December 1982 to December 1983, by over 2 percent in 1984, and again by over 2 percent in 1985 (9). Experiencing some of the sharpest drops in employment were licensed practical nurses and ancillary nursing personnel, dietitians, and dietetic technicians.

In general, changes in hospital staffing patterns reflect the increase in average "intensity of care" that has occurred over the past several years. Employment of less-trained hospital personnel has been reduced, while highly trained personnel have experienced substantial gains in employment nationwide. Registered nurses, pharmacists and pharmacy technicians, social workers, and, especially, respiratory therapists are examples (146). There are, however, important variations across occupations, types of hospitals, and geographic areas.

As pressure mounts to release patients quickly (i.e., either to discharge them from the hospital or to transfer them to less intensive care), the patients who must remain in the hospital and in the ICU tend to be, on average, sicker. They require more nursing care, more physician services, and more technology (32). In community hospitals of all sizes, the staff-to-patient ratio increased between 1983 and 1984 (146).

Cost-containment pressures and demographic changes are creating a hospitalized elderly population that is not only sicker, but also, on average, *older* than before. Health Care Financing Administration (HCFA) data for 1981 and 1984 reveal higher proportions of patients in all age groups over 75 (39) and, among all hospitalized Medicare patients, an overall average increase in age of about 6 months (125). This finding highlights the need to upgrade geriatric expertise among hospital staff generally.

Changes in the relative numbers of different kinds of professionals within the hospital bring changes in roles and responsibilities. Because of overlap in the training of personnel at different levels, more highly trained personnel are frequently able to perform many of the tasks of lower level personnel. The reverse, however, is not true. Consequently, some lower level personnel may be seen as dispensable, and the more highly trained personnel who are retained may be required to assume new or additional roles within and/or outside their own specialty. When the ICU census is low, for example, it is common practice (and "can be a source of disillusionment, frustration, and increased stress") to "pull" critical care nurses from the ICU and reassign them to other units (29).

The extent to which changes in hospital staffing patterns have reduced cost and improved efficiency or, alternatively, reduced the quality or availability of care is not known; the potential exists, however, for all these effects. Also, shifts in roles and responsibilities from one profession to another are likely to necessitate new or additional in-service training. At the same time, reduction in the numbers of personnel and incentives for increased productivity leave less time and fewer resources to do this training. Unstable hospital staffing levels and patterns and changed responsibilities also create interdisciplinary competition[11] and fears of layoff or unemployment that may affect staff morale.

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[9] It takes about 3 years for the effects of changes in reimbursement policy to be documented in data because of variations in the start of hospitals' fiscal years (when they start to use the new system) and time needed for the Health Care Financing Administration (HCFA) or others to collect and analyze the data (73).

[10] Labor costs constitute roughly two-thirds of all hospital costs (90).

Nursing Homes

The growth of the elderly population, especially the population over age 85, and pressures for early hospital discharge have dramatically increased the need for beds in skilled nursing facilities (SNFs). It is projected that the total need for nursing home beds (in all kinds of facilities) will soon double, from 1.55 million to 3 million. This includes expected growth in SNF beds of 8 percent between 1986 and 1987 alone (30). Obviously, more occupied nursing home beds create the need for more nursing home personnel.

Another change with important implications for both personnel and training is that some nursing homes are beginning to provide a higher level of care than they provided in the past. The use of life-sustaining technologies that were already available in a few SNFs (e.g., total parenteral nutrition and dialysis) is expanding, and other technologies that are new within this setting (e.g., mechanical ventilation) are being introduced. At least one nationally known proprietary chain reports that it is increasing the size of its nursing home staff and training employees to provide higher levels of patient care (126).

Personnel and training needs in nursing homes are closely tied to Medicare decisions about which technologies to cover in the nursing home setting and the extent to which the level of reimbursement gives nursing homes sufficient financial incentives to make this care available. Some observers believe, for example, that Medicare payment for total parenteral nutrition (TPN) is too low (43). In general, Medicare criteria for payment of life-sustaining treatments outside the hospital are complex, restrictive, and subject to variation in interpretation by claims reviewers (91).

To the extent that Medicare fails to cover or provides inadequate coverage for nursing home patients requiring life-sustaining technologies, Medicaid policies will become increasingly important. Under Medicaid, States have considerable influence over what technologies will be covered and, thus, what personnel will be needed in nursing homes. To accommodate patients dependent on life-sustaining technologies, a few States have augmented skilled nursing care with a new category of "very skilled nursing care." For example, Illinois' Public Aid Code has been amended to include coverage for "exceptional medical care," defined as follows:

> . . . the level of medical care required by persons who are medically stable for discharge from a hospital but who require acute intensity hospital level care for physician, nurse and ancillary specialist services.
>
> —Illinois Public Aid Code, Sec. 5-4.1

It is generally acknowledged that many nursing homes are not adequately staffed to provide complex services. To care for greater numbers of patients who need complex services, nursing homes would require higher staff-to-resident ratios and staff training (31). Provision of more complex services in nursing homes also has implications for personnel who are not based in the nursing home (e.g., respiratory therapists and nephrology social workers) but who will increasingly be asked to care for patients in this setting. The extent to which hospital personnel may be moving into nursing homes is not known, but this may be an important factor as hospitals and nursing homes establish closer ties.

Home Health Care

The effects of cost-containment on changing employment patterns and requirements are perhaps nowhere more apparent than in home care. Industry experts predict the high-technology segment of home care will grow very rapidly and dramatically (58,91). As both investor-owned companies and hospitals expand into the home care market, there will be a significant impact on the use of and need for highly skilled personnel in the home.

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[11] Such changes also fuel interprofessional rivalries when one profession is viewed as "encroaching" on the professional territory of another or where there exists "an environment of insecurity that has forced [some professions] to scurry around" in a frantic effort to justify their existence to hospital administrators (51).

Historically, registered nurses, licensed practical nurses, and home health aides, through their participation in public health agencies and visiting nurse associations, were the central figures in home health care programs. Today, nurses are still crucial, but other professionals and specialists, including respiratory therapists and intravenous therapy nurses, have been added to the home health care team. Also, for those health professionals who are accustomed to working in home care, there are new responsibilities and training needs associated with caring for patients who are often more acutely ill and who require high-technology care.

Clinical knowledge generally transfers well from the hospital to other settings, but in the home some special problems arise which health professionals must be prepared to handle. For example, supplies and equipment may not be readily available in the home, or there may be problems maintaining sterile conditions. These are exigencies that should be addressed in professional training or for which some type of provision must be made in practice. Otherwise, the quality of patient care is likely to suffer. The most important factors are probably lack of standards (102); lack of supervision; and lack of interaction with colleagues and advisors who would provide stimulation, informal peer review, and consultation.

Medicare coverage of life-sustaining technologies and the personnel who can provide them in the home is restricted and complex. To be eligible for any home health care benefits under Medicare, an individual must be homebound, must be under the care of a physician, and must require "intermittent" (and not full-time) skilled nursing, physical therapy, or speech therapy. For some technologies, Medicare regulations have not been issued; some regulations have been repeatedly modified to meet changes in technology; others are open to different interpretations by individual claims examiners.

Another problem is the uneven treatment by Medicare of different technologies in the home. Allowed charges for dialysis and the personnel who provide it, for example, are at least 80 percent reimbursed by Medicare; mechanical ventilation is similarly covered, but respiratory therapists are not; and intravenous antibiotic therapy is specifically excluded from Medicare home health benefits. Nursing services associated with intravenous antibiotic treatment could be covered, but this technology often requires more than intermittent nursing care (74). TPN and enteral nutrition can be covered in the home under the Medicare Part B prosthetic device benefit, but not under the Part A home health benefit. Thus, an approved home health agency that offers these treatments ceases to function as a home health agency; rather, it is seen by HCFA as a prosthesis supplier and, therefore, can receive no additional reimbursement for personnel.

Medicare reimbursement levels for technologies in the home are related closely to charges for the devices and equipment and do not include allowances for the nonphysician personnel whose services are necessary components of the technology (80). This situation may affect the quality of care patients receive in the home because home health agencies and durable medical equipment companies are encouraged to reduce either the number of visits to the patient's home or the skill level of caregivers.

Clinical Training

All of the professions involved in the implementation of life-sustaining technologies require supervised clinical experience, ranging from informal on-the-job training for certain technicians to multiyear clinical residencies for physicians. Traditionally, in medicine, nursing, and the allied health professions, acute care hospitals have been the main site for clinical training.

Medicare, from its inception, has provided support for graduate education for physicians, diploma nursing schools operated by hospitals, and certain allied health programs operated by hospitals. Through payments for patient care and payments explicitly for education, Medicare is the single most important source of support for health professions education in hospitals. HCFA estimates that Medicare reimbursement for patient care alone provides approximately one-third of all support for health professions education in hospitals (144). Thus, Medicare payment policies have important effects on what training is available now and what will be available in the future.

In 1974, Medicare established annual cost limits on reimbursement for certain routine hospital costs. Because of recognition that routine hospital costs were higher in teaching hospitals, an exception was made to exclude the extra (education-related) costs from Medicare's cost limits. Beginning in July 1979 and 1980, respectively, the *direct* and then the *indirect costs* of education[12] were allowed to "pass through" the cost limits.

Under Medicare's Part A prospective payment system for hospitals mandated by the Social Security Amendments of 1983 (Public Law 98-21), direct and indirect costs of education remain pass-through items. The President's fiscal year 1986 budget, however, included proposals: 1) to freeze Medicare payment for the direct costs of medical education at the level received in the reporting year ending in 1984, and end all new funding for Title VII and Title VIII programs; and 2) to cut Medicare payment for the indirect costs by 50 percent and change the basis on which costs are computed. A near-freeze (an increase for inflation plus 1 percent) was implemented through administrative authority and has been in effect since July 1985. The fiscal year 1986 budget reconciliation act (Public Law 99-272 or "COBRA") omitted the freeze on direct costs and reduced reimbursement for indirect costs by approximately one-third rather than by one-half. The President's original budget proposals for 1987 sought to end payment of all direct costs of training except the salaries of interns and residents; this would eliminate *all* Medicare support for training in nursing and in allied health, as well as all overhead costs associated with training of residents. In its final form, the President's budget still sought to cut the indirect costs (108).

Unless alternative funding can be found, reductions in Medicare support will substantially reduce the ability of hospitals to maintain current levels, diversity, and quality of education and training. Although such reductions are one way to reduce the projected overall physician surplus, the specialties and professions in which there are present shortages will also be affected and, indeed, might be hit the hardest. Specialties and professions that generate relatively little in patient care fees (e.g., family practice and some allied health programs) would become much harder to subsidize out of reduced payments (144); and new programs, including geriatrics, are more likely than well-established ones to be targeted (108).

Public Law 99-272 exempts geriatric programs from the reimbursement limits placed on graduate medical education in other specialties. Generally, Medicare reimbursement to hospitals for direct costs of medical education is limited to a maximum of 5 years per trainee (the minimum number of years of formal training to satisfy specialty requirements for initial board eligibility, plus 1 year). Since fellows in geriatrics must complete a residency in a primary specialty (internal medicine, family practice, or psychiatry) before commencing geriatric training, it appeared that geriatric training was categorically disqualified for Medicare support. The exception for geriatrics extends the "initial residency period" that is eligible for Medicare funds for up to 2 years. While such special attention to geriatrics is noteworthy, the exemption does not actually change the reimbursement for geriatrics; it protects the reimbursement that was already available.[13]

Medicare's prospective payment system also affects in-hospital training of physicians, nurses, and allied health personnel. Hospitals and departments that have a tradition of subsidizing training through payments for patient care, particularly nonprofit hospitals, may find this unfeasible under prospective payment and the changes occurring in Medicaid and private health insurance. Prospective payment provides hospitals incentives to reduce all costs, especially affecting those training programs in which educational costs cannot be separately identified for direct support. Thus, hospitals are now actively reviewing their training programs in relation to productivity and efficiency of operations (74).

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[12] The *direct costs* of health professions education include salaries for faculty, support staff, and residents; conference and classroom space; additional equipment and supplies necessitated by teaching activities. The *indirect costs* of medical education (a proxy for the added complexity of care in teaching hospitals) include reduced productivity in patient service departments, more complex hospital management, and the higher utilization of services and tests performed in teaching hospitals (144).

[13] Hospital administrators and others who control decisions about how many training positions are allotted to each specialty have strong incentives to favor those specialties for which Medicare reimbursement covers the actual costs of training. Inclusion in the reimbursement formula of a measure of hours worked in the hospital results in relatively poor reimbursement for geriatric trainees, who may spend much of their time in other facilities. Thus, despite the exemption for geriatric fellowships, geriatric training slots are still likely to be perceived as financial liabilities in the total hospital training program.

The Bureau of Health Professions of the Health Resources and Services Administration conducted a pilot study to assess the impact of Medicare's prospective payment system on clinical education programs in medicine, nursing, and other health professions (64). Site visits to hospitals in four geographic locations revealed decreased patient census, shorter lengths of stay, sicker patient populations, and increased emphasis on staff productivity. One result is increased competition among the professions for clinical access in hospitals. Personnel employed by the hospitals visited were found to have less time to spend teaching or supervising students. Hospitals were beginning to require payment for staff time spent in teaching activities, or were reducing their involvement in teaching programs. Clinical programs in all the professions reported problems in providing the appropriate number and mix of patients with which students can obtain the necessary experience to complete their training. Shortened lengths of stay may also preclude the kind of comprehensive workup and monitoring that is frequently important in training.

In a 1985 survey, 79 percent of the more than 2,500 responding allied health education programs said that Medicare's prospective payment system for hospitals had had a "strong" impact on their clinical education program. The majority of program directors said the effects of the payment system were mixed, but 14 percent said the effects were entirely negative. Seventeen percent of the program directors reported that their clinical education programs were inactive or closed (10).

Efforts are underway to expand education and training into alternate clinical sites. However, financing is problematic because third-party payers have not traditionally covered costs related to education in nonhospital sites. Also, increased competition has constrained the willingness of organized outpatient systems like health maintenance organizations and home care agencies to incur these costs.

EVOLVING CREDENTIALS

Virtually all commentators agree that licensure and certification are needed to set standards for health care and to protect the life and safety of patients. There are, however, continuing controversies over the desirable degree of regulation, what should be regulated, and the frequency of licensure, certification, and accreditation review. Licensing is governed by the States, certification and accreditation by the professional agencies. Public programs, including Medicare, often adopt these standards as a basis for reimbursement (74).

All 50 States license physicians, registered nurses, practical nurses, and physical therapists. Some States also license nurse practitioners, social workers, and occupational, speech, and respiratory therapists. Certification is granted by professional boards and associations and serves to identify those practitioners who have met standards of special competence in a particular specialty area. Certification generally is not a requirement to practice; however, many hospitals use certification status as a standard in hiring or in granting staff privileges.

The objectives of credentialing health professionals extend beyond quality assurance. These objectives are diverse and may lead to disagreements about the need for certain credentials, including those now available to physicians in geriatrics, critical care, and some allied health occupations. Frequently, a profession seeks certification and licensure to "professionalize" itself and set entry barriers, to maintain and enhance income and prestige (74). Health care institutions, including hospitals, nursing homes, and home care companies realize that hiring professionals with special credentials, besides presumably assuring or improving quality of care, may offer economic advantages in the increasingly competitive and litigious health care environment. Such economic advantages, however, must be weighed against the higher costs associated with employing people with special credentials. Information presented below on the current status of credentials for health professionals involved in the care of life-threatened elderly persons suggests how rapidly change is occurring.

Credentials in Geriatric Medicine and Nursing

There has been much debate about whether or not geriatrics constitutes a distinct body of knowledge; where geriatrics belongs (e.g., as its own specialty, within internal medicine, or within family practice); and whether or not a distinct credential should be created to recognize competence in this field. In the absence of a credentialing system for geriatrics, there has been no way to identify physicians who have had geriatric training, no assurance that the geriatric training obtained in different institutions meets comparable standards, and no way to reliably estimate the current supply of geriatricians. Also, without a geriatric credential, the developing body of geriatric knowledge can be rather easily dismissed by the uninitiated or, perhaps worse, claimed by the opportunist.

The Institute of Medicine's 1978 study of geriatric education (77) recommended against creation of specialty certification in geriatrics. Agreeing with the official position of the American Geriatrics Society, the Institute of Medicine concluded that geriatric education should be mainstreamed and that the care of the aged should be the responsibility of appropriately trained primary care physicians. The Institute further stated that creation of a new medical specialty in geriatrics could draw attention, energy, and resources from nursing and the other health professions involved in caring for the elderly, suggesting a "medical solution to a largely social problem." The Association of American Medical Colleges and the Federated Council for Internal Medicine (59) were among the other bodies that officially opposed certification in geriatrics.

Since 1978, the science base and clinical importance of geriatric medicine have grown substantially. Recognizing this, in 1985 the American Board of Medical Specialties authorized the American Board of Family Practice and the American Board of Internal Medicine to offer certificates of added qualifications in geriatrics. The two specialty boards are working together to develop a joint examination, with plans to offer it for the first time in spring 1988 (122). Both boards have emphasized that in offering this certification, they are not creating a new subspecialty of geriatrics in family practice or internal medicine, but are simply creating a mechanism for recognizing merit and achievement in geriatrics.

Applicants for the certificate in geriatrics must first be certified by the American Board of Family Practice or the American Board of Internal Medicine. In addition, internists must either have completed a geriatrics training program, an advanced general medicine training program with emphasis on geriatric medicine, or have 4 years of experience beyond their general medical training. (Internists already certified in a subspecialty will need only 1 additional year of training.) Specialists in family practice must also first complete approved geriatrics training. Geriatrics training programs will be evaluated and accredited by the residency review committees for internal medicine and family practice.

The American Nurses' Association offers certification in 17 areas, including a generalist certificate in gerontological nursing and a certificate for geriatric nurse practitioners. The generalist certificate in gerontological nursing, available since the mid-1970s, is offered to licensed registered nurses who have successfully completed a standardized test and 2 years of clinical experience with the elderly. The geriatric nurse practitioner certificate is offered only to licensed nurse practitioners who have a master's degree in nursing and who have completed at least 9 months or 1 academic year of clinical and didactic training in a program that meets American Nurses' Association guidelines.

Although certification in geriatrics has been available to nurses for a number of years, questions remain about the level of competence these credentials represent (53). For programs leading to the generalist certificate, no specific didactic or clinical training in geriatrics is required and there is no formal system for accrediting the institutions providing the geriatric clinical experience. The focus of the generalist certificate, both in the content of the exam questions and in the eligibility requirements to sit for the exam, is long-term care of the elderly; competence in the care of the acutely or critically ill elderly is not evaluated. Similarly, nurse practitioner training and testing does not emphasize critical care nursing.

Credentials in Critical Care Medicine and Nursing

In 1985, the American Board of Medical Specialties approved a subspecialty of critical care medicine within each of critical care's parent medical specialties. Physicians who are first certified by either the American Board of Internal Medicine, Anesthesiology, Surgery, Neurological Surgery, or Pediatrics may seek certification of special competence in critical care medicine. Each board will have its own training requirements and separate examinations (118). In addition, the American Board of Emergency Medicine has applied to the American Board of Medical Specialties for approval of certification of added qualifications in critical care for specialists in emergency medicine (111). In most medical specialties, certification in critical care will be valid for 10 years (68).

Certification in critical care nursing has been offered by the American Association of Critical-Care Nurses' Certification Corp. since 1975. Any registered professional nurse with current registered nurse licensure and at least 1 year (1,750 hours) of experience practicing as a registered nurse in the care of the critically ill is eligible to apply. More than 23,000 registered nurses have passed the written certification examination, earning the credential of critical care registered nurse (CCRN) (44). This certification is recognized for 3 years, after which recertification applicants must provide proof they have completed specified continuing education or repeat the written examination. The American Nurses' Association has not, to date, approved critical care as a specialty (69).

Technology-Specific Credentials

Dialysis

Nurses and technicians may be certified in hemodialysis through the Board of Nephrology Examiners. However, the American Nephrology Nurses Association does not endorse that examination and is preparing a new, more comprehensive examination in nephrology. This will be pilot tested in May 1987 and is expected to be offered later that year to registered nurses who are licensed in the United States and who have at least 2 years experience in the field of nephrology (119).

Dialysis technicians receive extensive on-the-job training, but there are few formal training programs and no accrediting agency. Technicians are not required to be licensed, registered, or certified, although they may take the examination in hemodialysis offered by the Board of Nephrology Examiners.

Nutritional Support

Registered nurses may earn certification in parenteral and enteral nutrition through the National Board of Nutrition Support Certification, created in 1984. The first examination for certification in parenteral and enteral nutrition nursing was given in June 1985 to 100 applicants.

Dietitians who specialize in nutritional support must meet the American Dietetic Association's requirements for registration. These requirements include the completion of a 4-year university course in dietetics, nutrition, or food service management; clinical experience; and a passing score on a written examination. Every 5 years, dietitians who specialize in nutritional support must also complete 75 hours of continuing education. Registered dietitians may join the special practice group of the American Dietetic Association known as "critical care dietetics." It is expected that a process for dietitians to be certified in nutritional support will be set up very soon, and that the first examination may be offered in spring of 1988. As for nurses, this certification would be through the National Board of Nutrition Support Certification (63).

Pharmacists who specialize in nutritional support have completed either a 5-year baccalaureate program or postgraduate work for the doctoral degree (Pharm.D.). Nutritional support pharmacists are currently working with the American Pharmacy Association's Board of Pharmaceutical Specialties to establish a process for certification in parenteral and enteral nutrition. They hope to have this process in place by 1988 (28).

Resuscitation

The American Heart Association has developed medical standards for certification in both basic life support and advanced cardiac life support. Courses that meet these standards are offered to all health professionals (and to the lay public) by hospitals, other training centers, and by the American Red Cross. Individuals who complete the training are certified in basic or advanced life support. Certification and annual recertification is recommended for physicians and nurses; however, requirements vary widely from State to State, institution to institution, and for different health professionals. In most States, certification in resuscitation is not a condition for physician licensure (99). Some hospitals, however, make current certification in basic or advanced life support a condition for physician staff privileges; some require certification only for their ICU and emergency room staff (8).

The U.S. Department of Transportation developed and approves all basic training programs for emergency medical technicians (EMTs). This is a standardized, 81-hour course given by many police, fire, and health departments, and by some hospitals, medical schools, colleges, and universities. Individuals who have been certified in the basic EMT program may go on to train as EMT-paramedics. This training includes didactic clinical instruction, in-hospital practice, and a supervised field internship totaling approximately 1,000 hours (76). A certificate and/or associate degree is awarded on completion of training, and graduates are then eligible to sit for the certification examination. Recertification is required every 2 to 3 years (2). Some States require EMT-paramedics to pass additional tests for certification or licensure. A registration examination is administered by the National Registry of Emergency Medical Technicians. EMT-paramedic training is subject to approval by the American Medical Association's Joint Review Committee on Educational Programs for the Emergency Medical Technician-Paramedic (76).

Mechanical Ventilation

The respiratory therapist is usually a graduate of a 2-year associate degree program of a community college. Some hospitals offer 2-year certification programs, and some colleges and universities offer a baccalaureate degree in respiratory therapy. In addition to classroom work, a minimum of 1,000 hours training in a clinical setting is required (2). Registered nurses and others who have a baccalaureate degree in an appropriate science can complete training in 1 year (106). Individuals who complete a program approved by the Joint Review Committee for Respiratory Therapy and who pass the examination of the National Board for Respiratory Therapy receive the credential of registered respiratory therapist (RRT). Licensure provisions currently exist in approximately four States and are being sought in some others.

Respiratory technicians must complete a 10- to 12-month training program. Most of these are based in hospitals or technical-vocational schools (3). A graduate who passes the technician level examination of the National Board for Respiratory Therapy becomes a certified respiratory therapy technician (CRTT).

Life-Sustaining Antibiotic Therapy

In general, intravenous life-sustaining antibiotics may be administered by any registered nurse. There is a specialized credential in intravenous therapy, however, and some institutions—especially nursing homes and home care providers—require it. Since 1983, about 600 registered nurses have attained the credential of "certified registered nurse, intravenous" (CRNI) through the National Intravenous Therapy Association. The basic requirements beyond registration are 2 years of specialty practice and passing the certification examination (107).

FINDINGS AND IMPLICATIONS

Many issues related to the quality, availability, and cost of life-sustaining care, as well as issues that bear directly on treatment decisions, are directly linked to the supply of pertinent health professionals and to the content of their education and training. This chapter has focused on topics that concern both the primary care and critical care specialties. Federal policies have direct and indirect effects on a wide range of manpower and training issues, ranging from employment opportunities in professions that are "technology-dependent" to questions about the adequacy of education and training in geriatrics and the feasibility of providing complex care in nursing homes.

Several major conclusions can be drawn from this analysis. First, there is a severe shortage of physicians, nurses, and allied health professionals with expertise in geriatrics and gerontology. Despite direct Federal support for education and training in geriatrics, and increased public and professional awareness of its importance, the late start and persistent recruitment problems in geriatrics, together with the rapidly increasing elderly population, mean that the shortage of health professionals with expertise in geriatrics will probably persist. Reduced funding for health professions education would threaten what advances have been made and impede further progress.

Moreover, although a large number of geriatric patients receive care in an ICU, little or no crossover has occurred in the training of geriatrics and critical care personnel. There has been no formal initiative to integrate geriatrics and gerontology into the training of critical care physicians and nurses, and training focused on geriatrics seldom includes experience in critical care. The lack of integrated training in critical care and geriatrics may hinder communication among caregivers and may lead to inappropriate treatment.

The need for rapid expansion of the supply of geriatric specialists, expenditure of public funds and resources to accomplish this, and the recent dramatic changes in credentialing make research on geriatric manpower important. It would be useful, and potentially cost-effective, to have information for evaluating the response of students and practicing health professionals to the new educational and career opportunities in geriatrics and to any incentive programs that might be instituted to stimulate recruitment to geriatrics.

The curricula in medicine and nursing in general and, to a lesser extent, the allied health professions are beginning to change in response to the aging of the patient population, ethical problems posed by life-sustaining technologies, rapid development of new knowledge, and cost constraints. Newly introduced subjects including the humanities, death and dying, health law, and medical decisionmaking share problems of uneven institutional commitment, limited and undependable funding, inadequate faculty, and competition for curriculum time. The effects of curriculum change on patient care have, for the most part, been unevaluated.

Significant changes are occurring in staffing patterns within hospitals and other health care institutions. Some professions are experiencing layoffs; others have an increased workload and/or improved employment opportunities. Further staff reductions in certain categories are expected to be revealed as the effects of prospective payment are documented. Changes in staffing patterns have implications for the amount and quality of care it is feasible to provide. If personnel reductions occur on a large scale, unemployment problems must also be considered. With relative changes in personnel also come new or changed roles and responsibilities that may create the need for new or additional training.

Shifts in the settings in which life-sustaining technologies are provided also have important implications for employment patterns. For many categories of personnel, employment opportunities in hospitals are being reduced; other areas show strong growth. Nursing homes and home care agencies are beginning to provide more skilled care and, thus, will need additional highly trained personnel. Some health professions students and practitioners need special training to work in settings in which they are new and/or where acutely and terminally ill elderly patients are new. Such retraining could potentially assist displaced health professionals and improve patient care.

A patient population that is older and sicker, plus changes in the site of care and changes in staffing patterns, bring substantial changes in the care that is needed and the resources necessary to provide it. Such fundamental changes raise questions of quality assurance and create the need for continuing education of health professionals.

Interdisciplinary collaboration and effective teamwork cannot be assumed. Although there has been much talk about health care teams, and there is much evidence of their benefits, there is little training to make such teamwork a reality.

Finally, caregivers to severely ill elderly patients are under severe stress that can lead to dysfunctional behaviors, including diminished job performance. Health professions education poorly prepares caregivers to deal with death in a way that is most beneficial to patients and least harmful to themselves.

CHAPTER 10 REFERENCES

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Appendixes

Appendix A

Method of the Study

OTA's assessment "Life-Sustaining Technologies and the Elderly" was requested by the Senate Special Committee on Aging and the House Select Committee on Aging. It was preceded by a planning effort that identified relevant congressional concerns and established a tentative plan for the study. A project proposal was developed and approved by OTA's Technology Assessment Board in September 1984. Staff were recruited and hired, and work commenced in October 1984. The original staff consisted of a project director, three analysts, and two research assistants, with backgrounds in gerontology, social work, public health, and law.

In preparing assessments, OTA relies heavily on the advice and assistance of persons outside the Office. Each project has an advisory panel, which advises and assists staff throughout the course of the assessment. The panel suggests source materials, subject areas, and perspectives to consider; reviews drafts prepared by staff and contractors; helps interpret information; suggests conclusions based on the information prepared by staff; and offers advice in the development of policy issues and options. Panelists do not, however, determine the final form or content of an assessment, and they are not responsible for its conclusions. Other important contributors to an assessment include the numerous individuals who serve as contractors and reviewers, providing resources and valuable technical assistance in their areas of expertise.

The advisory panel for "Life-Sustaining Technologies and the Elderly" consisted of 20 individuals with backgrounds in medicine (especially geriatrics), biomedical ethics, long-term care, health economics, health law, and technology development. Their expertise and experience included the full range of treatment settings in which life-sustaining technologies are used and the diverse viewpoints of patients, families, and professional groups involved in the care of life-threatened elderly persons. John W. Rowe, M.D., of Beth Israel Hospital and the Harvard Medical School, served as chairman. (Members of the panel are listed at the beginning of this report.) Between March 1985 and February 1986, three panel meetings were held. The panel meetings were open to the public, and some observers attended each meeting.

At the first panel meeting, March 15, 1985, discussion focused on the scope of the assessment and identification of the major issues to be addressed. The panel considered staff's preliminary outline for the assessment, and agreement was reached that the focus would be on five technologies, namely, cardiopulmonary resuscitation, mechanical ventilation, dialysis, nutritional support and hydration, and life-sustaining antibiotic therapy. It was further decided that there would be a chapter on each technology, plus chapters on the legal issues, the ethical issues, and one on manpower and training issues.

To augment in-house research, project staff solicited proposals and awarded contracts on each of the five technologies; on future developments in life-sustaining technologies; on legal issues and ethical aspects of decisions about life-sustaining technologies; on manpower and training for the selected technologies; on the clinical economics of nutritional support and life-sustaining antibiotic therapy; and on patient classification systems. OTA also awarded contracts for background papers on the use of life-sustaining technologies in six other countries. (The final reports for each of the contracts, as listed at the end of this appendix, may be obtained from the National Technical Information Service in Springfield, VA.)

By integrating the work of contractors with their own research, OTA staff prepared an initial draft of the report and sent it to the advisory panel for review. This draft was considered in detail at the second meeting of the advisory panel, held October 21-22, 1985. One topic of the meeting was how much technical and clinical detail about the technologies should be included in the report to support and inform discussion of the public policy concerns relative to the technologies. Another major topic of discussion was the use of age as a criterion in decisions about life-sustaining treatments.

In addition to being reviewed by the advisory panel and by project staff, individual draft chapters were reviewed by OTA staff not connected with this assessment and by a large number of other individuals. External reviewers are listed in appendix B.

Project staff made additions and revisions to the draft chapters based on suggestions and comments of all reviewers and sent revised drafts to the advisory panel. At the final meeting of the advisory panel, February 4-5, 1986, these revised draft chapters were reviewed. The panel made suggestions about the areas of emphasis and organization of the final report and discussed Federal policy options. The panel proposed and reached consensus on a series of general principles to guide decisions about life-sustaining treatments and suggested that these be included in the final assessment (see ch. 1).

Following the third panel meeting, the report was substantially revised and subjected to additional external review. It was then approved by the Technology Assessment Board and submitted to the requesting congressional committees.

OTA held two workshops in conjunction with this assessment. The first workshop was on "Making Medical Decisions for Mentally Impaired Adults." It was a joint undertaking of this assessment and the OTA assessment on dementia and was held on Sept. 23, 1985. Participants at the workshop, listed below, reviewed two contractor documents, "Surrogate Decisionmaking for Elderly Individuals Who Are Incompetent or of Questionable Competence" and "Withholding and Withdrawing of Life-Sustaining Treatment for Elderly Incompetent Patients: A Review of Court Decisions," and discussed methods for improving surrogate decisionmaking for decisionally incapable adults. In response to the recommendation of the workshop participants, OTA subsequently contracted for a third background paper, "Legal Perceptions and Medical Decisionmaking." Excerpts from all three documents were published by *Milbank Memorial Fund Quarterly*, Vol. 64, Supplement 2, 1986.

The second workshop held in conjunction with this assessment was on "Classification Systems for Decisionmaking for Critically Ill Elderly Patients," held May 14, 1986. The workshop participants, listed below, reviewed a contractor report on classification systems and discussed the use of chronological age in existing classification systems and the validity and usefulness of these systems for individual treatment decisions.

Some conclusions of both workshops are included in this report on Life-Sustaining Technologies and the Elderly. For detailed analysis of the topics, the interested reader is encouraged to refer to the contractor documents, which are available from the National Technical Information Service.

Workshop Participants

Making Medical Decisions for Mentally Impaired Adults, Sept. 23, 1985

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Contracts Written for OTA and Where They Can Be Obtained

The contract papers written for OTA's assessment *Life-Sustaining Technologies and the Elderly* have been compiled in five volumes that are available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA, 22161; phone (703) 487-4650.

Life-Sustaining Technologies and the Elderly: Working Papers, Volume 1: The Technologies, Part 1

"Cardiopulmonary Resuscitation in the Elderly," by Christine K. Cassel, Marc D. Silverstein, John LaPuma, Michael McCally, Dianne Roland, Mary Ahern, and Suzanne Mitchell, Center for Clinical Medical Ethics, Pritzker School of Medicine, University of Chicago, Chicago, IL.

"Prolonged Mechanical Ventilation," by Allen I. Goldberg, with contributions by Lu Ann Aday, Marlene J. Aitken, Augusta Alba, Robert J. Byrick, Candice Clark, Susen Dunmire, Donna Frownfelter, Sam P. Giordano, Bernard Goldstein, Frank J. Indihar, Gini Laurie, Margaret Pfrommer, Howard Robboy, and Ed Roberts, for Care for Life, Chicago, IL.

"Hemodialysis, Peritoneal Dialysis, and Related Therapies for Renal Dialysis and the Elderly/Technology," by Christopher R. Blagg, Northwest Kidney Center, Seattle, WA.

"Renal Dialysis Decisionmaking," by Richard B. Freeman, University of Rochester Medical Center, Rochester, NY.

"Report on the Treatment of Elderly Patients by Dialysis and Transplantation in Europe," by S. Challah, European Dialysis and Transplant Association, London, U.K.

Life-Sustaining Technologies and the Elderly: Working Papers, Volume 2: The Technologies, Part 2

"Nutritional Support and Hydration for Critically and Terminally Ill Elderly," by David A. Lipschitz and Ronni Chernoff, John L. McClellan Memorial Veterans Hospital, Little Rock, AK.

"Nutritional Support and Hydration for Critically and Terminally Ill Elderly," by Lyn Howard, with contributions by Lenore Heaphey, Michael Wolff, Jean Bigaouette, John Jenks, Liva Jacoby, John Balint, Michael Caldwell, and C. Richard Fleming, for the Oley Foundation, Albany Medical Center, Albany, NY.

"Antibiotics and the Elderly," by David W. Bentley, William H. Barker, Kathryn M. Hunter, Peter D. Mott, Charles E. Phelps, and Patricia A. Tabloski, University of Rochester and Monroe Community Hospital, Rochester, NY.

"Technology Assessment on Future Developments in Life-Sustaining Technologies for Elderly," by Yukihiko Nose, Makoto Usami, Takashi Horiushi, and Paul Malchesky, for the International Center for Artificial Organs and Transplantation, Cleveland Clinic Foundation, Cleveland, OH.

"The Clinical Economics of Nutrition Support Services and Antibiotic Medications for the Critically and Terminally Ill Elderly," by Deborah S. Kitz, Henry Glick, and John M. Eisenberg, University of Pennsylvania, Philadelphia, PA.

Life-Sustaining Technologies and the Elderly: Working Papers, Volume 3: Legal and Ethical Issues, Manpower and Training, and Classification Systems for Decisionmaking

"An Ethical Analysis of Withdrawal From Life-Sustaining Technologies and Assisted Death," by James F. Childress, Department of Religious Ethics, University of Virginia, Charlottesville, VA.

"Distributive Justice and the Allocation of Technological Resources to the Elderly," by Robert M. Veatch, Kennedy Institute of Ethics, Georgetown University, Washington, DC.

"Life-Sustaining Technologies and the Elderly: The Legal Issues," by Connie Zuckerman, Montefiore Medical Center, Bronx, NY.

"Geriatric Expertise in the Context of Critical and Terminal Care," by Patricia Barry and Lawrence Markson for the American Geriatrics Society, New York, NY.

"Manpower for Selected Technologies," by Ruth S. Hanft, Catherine C. White, and Linda E. Fishman for Ruth Hanft Associates, Washington, DC.

"Classification Systems for Decisionmaking for Critically Ill Elderly Patients," by Robert W. Gage, Stanley Lemeshow, and Jill S. Avrunin, University of Massachusetts, Amherst, MA, and Daniel Teres, Baystate Medical Center, Springfield, MA.

Life-Sustaining Technologies and the Elderly: Working Papers, Volume 4: Use of Life-Sustaining Technologies in Other Countries

"Legal Issues: Italy," by Emily C. Moore, Rome, Italy.

"Elderly in Japan," by Rihito Kimura, Kennedy Institute, Washington, DC.

"Legal Issues: Canada," by Holly Dugan, Johns Hopkins University Center on Aging, Baltimore, MD.

"Legal Issues: Yugoslavia," by Christoph Haug, Johns Hopkins University Center on Aging, Baltimore, MD.

"Legal Issues: Federal Republic of Germany," by Christoph Haug, Johns Hopkins University Center on Aging, Baltimore, MD.

"The Medical Care and Treatment of the Critically Ill Elderly in China: Issues and Lessons for American Policies," by John Langenbrunner, Washington, DC.

Philosophical, Legal, and Social Aspects of Surrogate Decisionmaking for Elderly Individuals, May 1987

"Surrogate Decisionmaking for Elderly Individuals Who Are Incompetent or of Questionable Competence," by Allen Buchanan, Department of Philosophy, University of Arizona, AZ; and Dan W. Brock, Department of Philosophy, Brown University, RI.

"Withholding and Withdrawing of Life-Sustaining Treatment for Elderly Incompetent Patients: A Review of Court Decisions and Legislative Approaches," by George J. Annas and Leonard H. Glantz, Boston University Schools of Medicine and Public Health, MA.

"Legal Perceptions and Medical Decisionmaking," by Marshall B. Kapp, Department of Medicine in Society, Wright State University, Ohio; and Bernard Lo, Department of Medicine, University of California, San Francisco, CA.

"Philosophical Issues Concerning the Rights of Patients Suffering Serious Permanent Dementia," by Ronald Dworkin, Department of Philosophy, University College, Oxford, England.

Appendix B

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Appendix C

Future Developments in Life-Sustaining Technologies

Introduction

Future developments in life-sustaining technologies will improve existing technologies and create new therapies and devices to treat currently untreatable conditions. Technological improvements should make treatments more effective, more comfortable, more portable, cheaper, less invasive, or some combination of these factors. These improvements may change how often and under what circumstances certain life-sustaining technologies are used, and they may contribute to changing attitudes about appropriate care. However, fundamental questions of access to and quality of care, cost, quality of life, and decisionmaking will remain even as the technologies change.

This appendix describes the general directions of current research and development, both in the public and the private sectors, that are pertinent to the use of life-sustaining technologies for elderly patients. Areas in which basic research is crucial to further progress are highlighted.

Factors Affecting the Demand for Life-Sustaining Technologies

The demand for new life-sustaining technologies will depend on a variety of factors, including the degree to which preventive strategies are implemented, the size of the potential patient population, reimbursement policies, and attitudes about the extension of life. Numerical projections of the groups at risk for the five life-sustaining technologies discussed in this report are not attempted, because of the lack of data on current use of the technologies and because the size and composition of future patient groups will be determined in large part by the availability and use of various new preventive, diagnostic, and therapeutic technologies. The effects of those treatments yet to be developed are impossible to gauge. Nevertheless, given both the growth and the aging of the elderly population, an increase in demand is likely.

The future social context in which technological development will occur and health care decisions will be made is also uncertain. The Institute for the Future, a private research and consulting firm in Menlo Park, CA, recently developed two possible scenarios to show the wide range of possibilities. These are not predictions of what the sociopolitical environment will be, but rather indicators of the wide range of factors that might influence health care decisionmaking and the development of new life-sustaining technologies (47).

One scenario, entitled "Cost Containment," envisions the development of societal consensus to contain health care costs. The consensus is sustained by the relatively young, college-educated, baby-boom group whose needs center more on housing, education, and child care than on health; the competitive climate for business; the concern over government deficits; and the public's sharp eye on the public purse and the family budget. In this scenario, total health care expenditures as a percentage of gross national product (GNP) remain at their 1983 level in the year 2000 (47).

In the other scenario, entitled "People Want More," the historic pattern of growth in the health care system continues despite efforts to contain costs. The demographic, attitudinal, technological, political, and economic forces assumed in this scenario create pressures to provide a wider range of health care services to an aging population. Progress is made in treating a variety of diseases. People accept the value of these interventions and demand that they be made available. The result is widespread support for an expanding range of chronic care, acute care, and rehabilitation services. Somewhat paradoxically, say the authors of this scenario, the hospice movement will continue to grow because there will still be many illnesses for which the limits of medical science are obvious to the public (47).

The burden of chronic illness in the years to come is also impossible to foresee. One major theory holds that although the incidence of chronic disease may increase, the average age at onset and the disabling effects of these diseases will increase faster than will life expectancy. This would produce a "compression of morbidity" in which the average period of chronic disease and disability in old age will be less than current levels. Another scenario foresees longer average periods of disability and chronic illness in the future, based on the assumption that recent lifesaving and other health care technologies have lengthened lives more than they have reduced the incidence of chronic diseases (87).

Factors Affecting the Availability of Life-Sustaining Technologies

A spectrum of individuals and organizations plays a role in the development of medical technologies. Patients and clinicians identify and define specific medical problems that may be controlled, cured, or compensated for technologically. Biomedical engineers and others apply their expertise to identified clinical problems. Some technologies are not so much a result of physiological understanding as they are a triumph in solving a vexing technical problem.[1] Other developments require better understanding of physiology. Once a useful drug or device has been developed, a manufacturing company must assess a variety of factors and make a decision about whether to produce and market the technology.

Research and Development

Biomedical research and development (R&D) is focused on understanding physiological processes and developing cures or prostheses to use when these processes are pathological. Some R&D is specific to a particular technology, while some will affect several technologies. Computerization and new biocompatible materials will have applications in most if not all of the technologies described in this report. The "skin button," for example, can be used in dialysis, nutritional support, intravenous (IV) antibiotic therapy, and other treatments that require vascular access. (See box C-1.)

Box C-1.—The Skin Button

The "skin button," a vascular access device, reduces the complications of long-term catheter use. Thermoelectron has begun marketing a thimble-sized device that provides a permanent and theoretically infection-free port between the body and the outside world. Generally, catheters for parenteral nutrition, dialysis, drug delivery, and other uses are inserted into the body directly via incisions in the skin; a frequent complication of catheterization insertion is the growth of skin cells around the catheter, creating a tunnel into the body that provides a conduit for infection (36,20).

The "skin button" uses a proprietary polyurethane called "Tecoflex," which allows skin cells to grow into the device's porous surface and produce collagen, thereby creating a "healed" barrier between the skin and the device. Once implanted, catheters may be threaded through the button an unlimited number of times. The device can also be used to provide electric power to artificial internal organs, to stimulate muscles and nerves, or to control pain (83). The National Heart, Lung, and Blood Institute supported the development of this technology via its Devices and Technology Branch (69).

A similar device is the Hemasite II Vascular Access System, manufactured by Renal Systems, Inc. Designed specifically for dialysis, the device consists of an implantable shunt, made of a biocompatible titanium-based alloy, and a double cannula access set, which plugs into the shunt to provide an external pathway for blood flow. The device eliminates needle punctures, since the access set is inserted into the shunt, not into the skin. Not only is access painless, but complications associated with percutaneous needle punctures, such as hematomas, tissue and vessel scarring, infiltration, post-dialysis bleeding, and vessel deterioration, are eliminated (71).

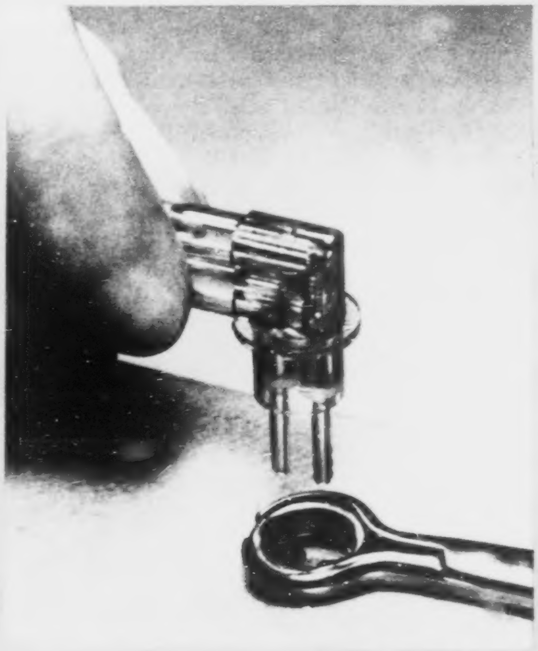

Photo credit: Renal Systems, Inc.

The Hemasite II Vascular Access System provides access for hemodialysis without the necessity of puncturing the skin each time. The implanted "button shunt" is made of biocompatible materials that do not react with tissues. The exit site wound heals tightly around the device to help prevent infection.

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[1] A nuclear-powered cardiac pacemaker is an excellent example of engineering ingenuity that solved a power-supply problem.

Biocompatible materials are required in almost all of the technologies discussed in this report. New materials could be used for a variety of purposes, such as smaller, more comfortable feeding tubes or dialysis membranes that more closely mimic the action of the kidney. Biocompatible materials can be made from a variety of substances, including ceramics, polymers, cellulosics, and metals (17,43,51).

Computers also have increasing applications. Computers are being applied to infusion pumps to assure proper delivery of antibiotics and nutritional formulas, to defibrillators to automatically provide the appropriate electric shock, and to blood gas monitors, important in mechanical ventilation. Metabolic monitoring systems can measure oxygen consumption and carbon dioxide production, using computers for data storage and graphics (12).

In addition to treatment technologies, computers will have applications in prognosis and decisionmaking. Assimilating the immense amount of information pertinent to clinical decisions and selecting from many potential treatments is becoming increasingly difficult as the knowledge base grows. New techniques referred to as "decision analysis," "medical decisionmaking," or "clinical decisionmaking" are being developed to systematize decisionmaking and objectify uncertainty (see ch. 10). "Expert systems," computer systems that are programmed to approximate human thought processes, will increasingly aid physicians in making diagnoses and prescribing treatments. Computer networks and databases are evolving to link physicians with information about treatment modalities and outcomes. Computers can store and sort the constantly increasing amount of medical information (2), allowing physicians to keep up with and add to the expanding knowledge base.

An example of a computer application relevant to the technologies discussed in this report is the computer surveillance of hospital-acquired infections and antibiotic use. One study showed that computer screening to identify patients most likely to have infections can find more infections faster than traditional methods (31). Timely control measures are believed to be important for interrupting the spread of hospital-acquired infections (31).

Eventually, home health monitors might incorporate a microprocessor with reservoirs of drugs and electronic probes. Several prognosticators envision a "hospital on the wrist," a wearable, miniature health monitoring device that could sense changes in the body and administer drugs or therapeutic electrical charges automatically (8,59).

New power sources are also an important area of research. Power sources are currently an important issue for pacemakers, defibrillators, and cardiac prosthesis and assist devices. Compact power sources will be needed for implantable or portable devices.

Production, Diffusion, and Use of New Medical Technologies

Development of a new technology does not always result in its availability. A drug or device that has been determined to be technologically feasible (from an engineering and production standpoint) must still pass through a complex and lengthy approval process to become commercially available. Once new drugs, devices, or procedures are available, health care providers must make decisions about adopting or investing in them. Those decisions are influenced by a variety of factors, including the general climate of the health care industry.

Several analyses foresee longer development times for new technologies in the coming years, due at least in part to increasing emphasis on cost containment. Industry's willingness to support equipment-related R&D is expected to decline as more hospitals forgo expensive equipment purchases whose cost-effectiveness has not been clearly demonstrated (11,63).

Economic influences sometimes prevent the development of socially desired drugs and medical devices. For instance, the potential profitability of a drug that treats only one disease of low incidence may not provide pharmaceutical companies with adequate incentive to bear the expense of development.[2]

In addition, once a drug or device enters the testing and approval-seeking stage, various Federal agencies influence its ultimate availability. The National Institutes of Health (NIH) may support randomized clinical trials; the Food and Drug Administration (FDA) evaluates safety and efficacy prior to commercial distribution; the Health Care Financing Administration (HCFA) determines Medicare coverage and reimbursement.

As technologies are marketed, the role of third-party payors in determining the fate of drugs and devices should not be underestimated. In some situations, reimbursement policies have contributed to the overuse of certain medical technologies. Other factors that sometimes encourage overuse of medical technologies include competition among hospitals to attract patients and physicians, public demand for sophisticated technologies, increasing specialization within medicine, physicians' desire to do as much as possible for their patients, and uncertainties related to what constitutes appropriate use. The threat of malpractice suits can also encourage the overuse of medical tests and procedures (85). In addition, the promise of new technologies has at times lured providers into creative financing and partnership arrangements so they can gain access to a major new technology—in spite of certificate-of-need limitations or other-regulatory obstacles (77).

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[2] Congress enacted the Orphan Drug Act of 1983 (Public Law 97-414) to create additional incentives for the development and production of drugs and devices for treating rare diseases and conditions.

Alternative Treatment Settings

Many providers and manufacturers are investigating alternate-site care, to replace or supplement traditional inpatient hospital care. They hope to develop more cost-effective ways of providing health care and to identify new markets. As competition and cost-containment efforts in the health care industry intensify, technologies useful in alternate-site treatment will become increasingly important. The health care industry has recognized these opportunities, as reflected in a series of reports analyzing nonhospital providers (40) and the increased production of devices intended for home use (e.g., larger IV bags to last through the night). Reduced size and increased portability of medical equipment will facilitate the use of various technologies in nonhospital settings.

Among the settings receiving increased attention are nursing homes, patients' homes, and ambulatory care centers, including pain management centers and diagnostic imaging centers. Each of these sites provides opportunities for technological innovation and increased involvement of lay personnel and less trained health professionals. However, the adoption and use of technologies suitable for either home or outpatient use is often limited by reimbursement policies. For example, lack of Medicare coverage for IV antibiotics at home may limit the use of this technology for elderly patients (see ch. 9).

Future of Resuscitation

In spite of the proven value of cardiopulmonary resuscitation (CPR) as a life-saving procedure, resuscitation remains fraught with potentially severe problems and complications, and it is often unsuccessful. As discussed in chapter 5, resuscitation involves two stages: basic and advanced life support.

Basic Life Support

Current research in the area of basic life support focuses on developing techniques to improve ventilation and blood flow in the event of cardiac arrest, reduce the number of CPR-related injuries, and improve survival across all diagnostic classes of resuscitation patients. Another area of research is the development of techniques to correct certain types of arrythmias (e.g., asystole or bradyarrythmias) that are difficult to treat with current CPR methods.

Efforts to improve basic life support are focused on modifying current techniques, rather than developing equipment. The most obvious areas of research are the duration of chest compression and the rate and timing of ventilation during CPR. Methods to improve blood flow during CPR, especially to the brain, are also under investigation. The risk of brain damage during CPR is very high because inadequate circulation of blood deprives the brain of needed oxygen.

New CPR is an experimental process that requires specialized equipment and endotracheal intubation. This more complex version of CPR combines chest compression and lung inflation with abdominal binding to increase pressure inside the chest. This pressure is transmitted up the carotid arteries to increase the flow of blood to the brain, thus minimizing the risk of brain damage. This model has proven successful in dogs and is being investigated in humans. Some success has also been reported with the use of pneumatic anti-shock trousers (as a means of abdominal binding) in increasing survival rates. The initial data showed slightly higher resuscitation and discharge rates with the use of pneumatic trousers but were statistically significant in only one group of patients (57).

Other variations on standard CPR under investigation include asynchronous ventilation; simultaneous ventilation and compression; intermittent abdominal counterpulsation; and high-frequency, high-momentum chest compression. All are designed to take maximum advantage of the mechanisms of blood flow. All of these approaches represent the broader and increasingly prevalent view of CPR as *cardiocerebropulmonary* resuscitation, a term that recognizes the goal of increased blood flow to the brain and the prevention of neurological deterioration from global ischemia (lack of blood flow) (74).

Open-chest cardiac massage is receiving renewed interest, although it was virtually abandoned following the introduction of closed-chest massage (standard CPR) in 1960. Some studies have demonstrated successful open-chest CPR following failure of closed-chest massage. In addition, some authors have noted that closed-chest massage was introduced and accepted because of its clinical usefulness and efficacy, but without any controlled studies to compare its efficacy with that of open-chest massage, or to determine the appropriate use of either procedure (74). Thus, additional studies of open-chest CPR may be warranted. Some clinicians, however, believe that the trauma of open-chest CPR is so great that the technique should be used only as a last resort. These clinicians warn that renewed interest in open-chest CPR may lead to its overuse (52).

Defibrillation, Antitachycardial Pacing, and Cardioversion

Since early defibrillation has been shown to be one of the most important factors in the favorable outcome of out-of-hospital cardiac arrests (84), many efforts in the last 20 years to improve CPR survival have been directed at shortening the time to defibrillation. Physicians and paramedics are the professionals most likely to be trained to defibrillate patients at the scene of the arrest. Programs are now being developed to train Emergency Medical Technicians (EMTs) and lay people in the use of automatic external defibrillators (13). These devices sense cardiac rhythms, generally through adhesive chest electrodes, and determine whether ventricular fibrillation is present. Some models automatically shock a patient in ventricular fibrillation: others allow the user to decide whether or not to deliver a shock. All operators must be trained in basic CPR, since proper resuscitation with such a defibrillator depends on the integration of both CPR and defibrillation.

The implantable defibrillator, a relatively new device, substantially improves the survival rates of patients who experience ventricular fibrillation. These devices are surgically implanted in patients known to be at risk of arrythmias: they monitor and respond automatically to aberrations in heart rhythms. The first implantable defibrillator to receive FDA approval is described in box C-2.

Two other implantable devices are useful for the automatic termination of ventricular tachycardia and fibrillation: antitachycardia pacemakers and low energy cardioverters. The pacemakers have been tested in clinical trials, and several models are available. Because of their lower energy requirements, low energy cardioverters are smaller than implantable defibrillators, but they have not been widely tested. Currently, both devices require the use of a defibrillator as a backup system, although the high energy produced by a defibrillator is not always necessary to terminate arrhythmia. Therefore, an ideal automatic electronic arrhythmia-terminating device should combine antitachycardia pacemaking, low energy cardioversion, and higher energy defibrillation. The ideal device would be fully programmable between these three modes of arrhythmia termination and incorporate automatic arrhythmia detection algorithms. Clinical trials of an implantable defibrillator with antitachycardia and regular pacing functions are expected in 1987 (10).

Box C-2.—Implantable Defibrillator

In October 1985, FDA approved a surgically implantable defibrillator to treat patients susceptible to ventricular tachycardia or fibrillation, particularly those who do not respond to conventional drug therapy (about 400,000 people annually in the United States). The mortality rate from sudden cardiac arrest for these patients is estimated to be 27 to 60 percent per year; in clinical trials (323 implants), the rate was reduced to 5 percent per year for patients with the implanted defibrillator (88). The cigarette pack-sized device, implanted in the abdomen, senses the rhythm of the heart via electrical leads attached to the heart muscle. If fibrillation or tachycardia is detected, it sends a series of electrical impulses to convert the arrhythmia into a normal rhythm—all in about 7 seconds (42). The device is powered by a battery that lasts about 2 years and then requires surgical replacement; efforts to extend battery life are underway (88). In addition, the defibrillator's functioning may be monitored by a physician with radio telemetry. The device and its associated medical costs are estimated to be between $20,000 and $25,000, and was approved for Medicare coverage early in 1986. Blue Cross and Blue Shield also cover the device, which had been used in about 1,500 patients as of February 1987 (79).

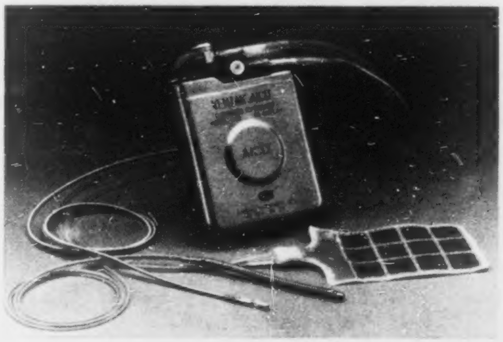

Photo credit: Cardiac Pacemakers, Inc.

The implantable defibrillator received FDA approval late in 1985 and was approved for Medicare coverage early in 1986. The pulse generator, a device the size of a cigarette pack, monitors cardiac activity and treats tachycardia and fibrillation by applying a counter shock through wire leads that are attached to the heart.

Drugs and Drug Delivery

Drugs play a significant role in resuscitation, and new methods of drug delivery are being developed. For instance, some observers suggest that the use of endotracheal administration of drugs during resuscitation deserves more attention (32). In cases where adequate intravenous routes cannot be located quickly, endotracheal administration may provide an important alternative for the delivery of epinephrine, atropine, lidocaine, and certain other drugs. (Drugs that require a large volume of fluid to achieve an effective dose—e.g., sodium bicarbonate—are unsuitable for endotracheal administration.) One advantage of the endotracheal route is its extended duration of action (two to five times that of intravenous administration). Also, it can be used by paramedics (or others) or when conditions preclude efficient intravenous access (32).

Another promising development in drug delivery is a new device to administer lidocaine. The device is about the size of a lipstick tube, costs approximately $15, and automatically injects lidocaine into a muscle when a safety cap is removed. This technique could prevent up to 30 percent of pre-hospital deaths from heart attack, depending on how quickly the lidocaine was administered, according to the director of one randomized controlled study (65). FDA has approved the device for emergency use by physicians and paramedics, or by certain heart patients who are undergoing remote monitoring (53,65). Oral analogs to lidocaine have also been developed (71).

Tissue-type plasminogen activator (t-PA) may also be administered by an automatic intrasmuscular injection device. Two companies are collaborating to develop such a device to permit patients to self-inject themselves with t-PA, a drug expected to gain FDA approval for dissolving blood clots associated with myocardial infarction (13).

Other new drugs may help reduce the risk of cardiac death for certain patients. One drug, flecainde acetate, received FDA approval in November 1985 for the treatment of life-threatening ventricular arrhythmias and for patients with symptomatic ventricular arrhythmias (3). FDA also approved the drug amiodarone hydrochloride for use in patients who would otherwise die from uncontrolled ventricular arrhythmias. This drug has very serious side effects and is described as "a drug of last resort, to be used by experts very familiar with the treatment of severe heart rhythm disorders and only after attempts to use alternative agents have failed" (4).

Heart Replacement and Assist Technologies

The use and success of heart transplants have greatly increased in recent years, largely due to the introduction of the drug cyclosporine, which helps prevent rejection of the new organ. Human heart transplantation has become so routinely successful that it is virtually perceived as a standard medical practice. Data from about 1,200 heart transplants worldwide indicate that 90 percent of patients revert from "severely compromised function" to "uncompromised function" after a successful transplant (26). Artificial heart implantation, however, is currently experimental and very controversial. Judging from the complications associated with the current generation of artificial hearts, it seems unlikely that artificial hearts will become widely available in the near future (27). Knowledge gained from artificial heart research may, however, be used to develop various forms of cardiac-assist technologies. In addition, cardiac-assist technologies may be useful in some patients for temporary cardiac support until a failing natural heart recovers, or until a suitable donor heart is available for transplantation. A variety of heart replacement and assist devices are under development or in clinical trials (table C-1).

Artificial Hearts.—As of November 1986, a total of 20 American patients had received artificial hearts. Four models have been used: the Jarvik-7; the Jarvik-70, a smaller model; the Penn State heart; and the Phoenix heart. The Jarvik-7 artificial heart has been tested in five patients as a permanent replacement. All four models of artificial heart have been used as a temporary prosthesis, until a suitable human heart was available (27).

The Jarvik-7 artificial heart is a pneumatically driven, plastic "pump" with a smooth, nonthrombogenic polyurethane interior surface to reduce the risk of blood clotting. Nonetheless, despite careful administration of anticoagulants, the patients who have received the Jarvik-7 have suffered complications resulting from blood clotting.

Attempting to overcome problems with the Jarvik-7, investigators have developed other approaches to a permanent artificial heart. In May 1985, FDA granted approval for the implantation of the "Penn State heart" in six patients—the second artificial heart approved for human implantation. The Penn State heart differs from the Jarvik-7 in that it is intended to be used as a temporary "bridge" to "eventual and timely [human] cardiac transplantation" (26).

Table C-1.—Heart Replacement and Assist Devices

Type	Status	Major Developers
Intra-Aortic Balloon Pump	FDA approved for clinical use	Datascope, Kontron, SMEC, Aries
Percutaneous Left Ventricular Assist Device	R&D, clinical trails[a]	Abiomed, Electro-Catheter
Emergency Left Ventricular Assist Device	Pre-clinical trials	Electro-Catheter
External Left Ventricular Assist Device	Clinical trials	Biomedicus, 3M, Novacor, Thermedics, Thoratec, Abiomed, Nimbus
Implantable Ventricular Assist System	Pre-clinical trials	Abiomed, Novacor, Thermedics, 3M, Symbion
Externally Driven Total Artifical Heart	Clinical trials	Symbion, Thoratec
Implantable Total Artificial Heart	R&D	Abiomed, Symbion, Thoratec, Cambridge Medical Technology

[a] Electro-Catheter's pulsatile pump, a major component of the cardiac assist device, has been used in clinical trials.

SOURCE: Biomedical Business International, Inc., *Cardiovascular Therapy Products*, Report #7027 (Tustin, CA: March 1987).

Major goals for the next generation of artificial hearts derive from the problems that have resulted during the first few implantations in humans. These goals include:

- development of an implantable power source useful for an extended period of time;
- construction from all nonthrombogenic materials;
- identification (or development) of effective and long-lasting valves; and
- elimination of infection and rejection problems.

At this time, it appears that the next generation of artificial hearts will have electrically powered motors, probably with the power delivered transcutaneously, to preclude the need for leads exiting from the body and providing more mobility for heart recipients (26,55). An early model of such a heart kept a calf alive for 222 days, until an electric component failed. Human trials are not expected until the 1990s (48,55).

Cardiac-Assist Technologies.—Many researchers are concentrating their efforts on options other than complete artificial heart implantation—although some of these technologies go hand in hand with artificial heart research—e.g., the left ventricular assist device (LVAD). Other technologies for cardiac assist include the biventricular bypass device, the intra-aortic balloon pump, and cardiopulmonary bypass surgery.

The left ventricle does about 80 percent of the heart's work. The LVAD is a potentially implantable pump that assists, rather than replaces, the heart's left ventricle. The natural left ventricle pumps the blood into the LVAD, which then pumps the blood back into the patient's circulatory system. A major advantage of the LVAD is that the natural heart is left in place and may be able to sustain circulation if the LVAD should fail. As of mid-1985, four makers of electric LVADs had received funding from the National Heart, Lung, and Blood Institute to begin preclinical testing of their devices; makers also received stipulations about minimum reliability requirements. Researchers have estimated that experimental LVAD implants in humans could begin as early as 1987 or 1988 (55); experimental implants of LVADs in animals have succeeded for up to 7 months (48).

Power sources have been a major obstacle to the development of LVADs and artificial hearts. Early models used an external battery pack that was connected to an implanted pump by a wire piercing the skin. Current models use electric coils (one implanted below the skin and one worn on the surface of the skin) to transmit electrical current inductively. The third generation of devices is expected to use thermal engines that are powered by energy provided by high temperature, encapsulated salts. Animal experiments are underway (16,48,55).

Other technical issues include the optimal material for implantable pumps, optimal location in the body for implantation of an artificial pump, the type of electrical system to use, and the means to regulate pulse rate.

Future of Mechanical Ventilation

Developments important for long-term mechanical ventilation include improved reliability, portability, ease of use, and comfort. Some research is geared toward simulating natural respiratory functions and, ultimately, toward developing a completely implantable artificial lung. The technologies likely to change the capabilities of acute ventilatory therapy range from variations on standard types of mechanical ventilation (e.g., high-frequency ventilation) to hybrids of new and old methods (e.g., extracorporeal membrane oxygenation, with low-frequency, positive-pressure ventilation).

Mechanical ventilation involves considerable deviation from the normal dynamics of spontaneous breathing and may be accompanied by dangerous side effects and complications. These include potentially harmful cardiovascular effects, damage to the lungs, uneven ventilation, disturbances of acid-base balance, constriction of cerebral blood vessels, and side effects to the kidneys or liver (48) (see ch. 6). To improve mechanical ventilation, these harmful effects must be minimized.

High-Frequency Ventilation

High-frequency ventilation (HFV) is a form of mechanical ventilatory support that differs from conventional modes of ventilation in both relative tidal volume (i.e., volume of gas exhaled in one breath) and respiratory rate (29). Recently, HFV has gained support based on the concept that oscillatory flow can accelerate diffusion and is adequate for gas transport (23). Although there is no uniform definition, HFV is usually characterized by tidal volumes less than or equal to anatomic dead space and frequencies at least twice the resting respiratory rate (1). HFV may be useful for elderly patients because of their likelihood of decreased regional lung compliance. HFV renders lung compliances relatively unimportant (29). However, despite the theories as to why HFV should work, the technique has shown surprisingly little success so far (38).

There are basically three kinds of HFV systems: open, closed, and pleural surface systems (29). In an open HFV system, a port is open to the atmosphere at all times to allow the escape of exhaled gases. This system requires no pneumatic seal at the airway opening; however, gas pressures and flows in the airway may still be adjusted (29). The airway in a closed HFV system is isolated from the atmosphere during the inspiratory phase of the ventilator cycle, thus assuring that the total tidal volume generated by the ventilator enters the respiratory system (29).

Recently, a new type of closed ventilator has been developed. The system is completely sealed and thus has the advantage that oscillatory pressure cannot leak from it. A portable HFV system using a miniature motor has been developed at NU-TECH Industries, Inc., with the assistance of a grant from the National Institutes of Health. The unit will provide 5 to 10 liters per minute of extra ventilation to elderly patients with chronic obstructive pulmonary disease, for example, without increasing the work of breathing by the patient. An improved system with a portable configuration, high reliability, and simple control features would greatly enhance long-term home treatment (48).

Pleural surface HFV systems employ oscillations at the chest wall rather than at the airway. This has the advantage of not requiring airway access but has the disadvantage that the transfer of oscillatory energy to the lung may be technically difficult. This technique may ultimately prove valuable in giving mechanical assistance to patients with incipient respiratory failure (48).

Experiments on laboratory animals showed that normal gas exchange can be maintained with this system for extended periods when the animals are anesthetized and paralyzed to prevent spontaneous breathing. A vest-like device for HFV by vibration of the chest wall is being tested on patients with respiratory failure (5).

Extracorporeal Membrane Oxygenation

Extracorporeal membrane oxygenation (ECMO) is a complex treatment for patients in acute respiratory failure. ECMO involves threading a tube into the heart to carry blood outside the body to an artificial lung machine, where the blood is oxygenated and then returned to the body. Oxygenation and removal of carbon dioxide are achieved using passive diffusion across a membrane similar to that used in hemodialysis. ECMO avoids the drawbacks of mechanical ventilation —high airway pressure and high oxygen concentration—while allowing the lungs to rest. In the early years of its development in the 1970s, available data suggested that ECMO increased the likelihood of survival for patients with certain types of acute lung injury (89). However, the use of ECMO in adults decreased rapidly as evidence began to suggest that although the technology can support respiratory gas exchange, it does *not* increase the probability of long-term survival in patients with severe acute respiratory failure (38,89).

There are fundamental limitations to this therapy, particularly for elderly patients. The best candidates for ECMO are patients in *reversible* acute respiratory failure; it has little therapeutic value for patients with chronic progressively deteriorating respiratory insufficiency, which may be more typical among elderly patients[3] (48). In addition, acute respiratory distress is often a manifestation of multiple organ failures (70); thus, the primary therapy may be more appropriately directed to other organs or organ systems. Finally, a major study found no improvement in survival rates with ECMO except in very special circumstances (79). However, experience with ECMO could ultimately lead to a portable artificial lung for long-term use (48).

Ventilation Supplemented by Extracorporeal Technologies

A relatively new approach for treating acute respiratory failure dissociates the two main respiratory functions, i.e., transport of oxygen and removal of carbon dioxide. Oxygenation is accomplished by *low-frequency, positive-pressure ventilation* (LFPPV), to cause diffusion through the diseased lungs and to preserve pulmonary mechanics and volumes. The carbon dioxide is extracted by use of an *extracorporeal membrane* through a low-flow bypass, thus preserving pulmonary blood flow. The goals of this technique (referred to as LFPPV-ECCO$_2$R) are to keep the lungs statically inflated to allow optimal oxygenation of blood, avoid the local and systemic complications of continuous positive pressure ventilation, and enable lung healing (37).

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[3] In contrast, ECMO is used for some infants with serious respiratory problems because their lungs are more likely to heal.

Another possible treatment method would use high-frequency ventilation (HFV) along with a new (as yet undeveloped) extracorporeal membrane. Gas exchange would occur through the lungs with HFV but would be supplemented by a low-flow gas exchange system using a variation on a dialyzing membrane. Hemodialyzers have been found quite effective for the removal of up to 50 percent of the carbon dioxide, but available membranes have a functional life of under 30 hours. The following improvements in oxygenation membranes will be necessary if such a system is to become a reality:

- gas exchange capacity should last at least 1 week, and the membrane should be easily replaceable at the end of its functional life;
- the membrane should have a small surface area and be constructed of highly biocompatible material;
- a simple, small, atraumatic pump that can function for at least 1 month must be developed; and
- a simple and small priming volume system is needed.

Development of a system meeting these criteria would allow the reduction (or elimination) of anticoagulant administration and enhance the likelihood of home treatment (48).

Peritoneal Oxygenation and Carbon Dioxide Removal

Another theory holds that peritoneal gas exchange of oxygen and carbon dioxide is possible through a method similar to peritoneal dialysis (see ch. 7). Although the oxygen transport capacity of the peritoneal membrane is small, it may be possible to augment this by using a red blood cell substitute with a high oxygen-carrying capacity. The red blood cell substitute would be saturated with oxygen and pumped into the peritoneal cavity. Oxygen then would diffuse down a concentration gradient into the tissues and blood supply of the peritoneum (7). Also, the use of a red blood cell substitute for peritoneal oxygenation may facilitate the removal of carbon dioxide, since some such substitutes have a relatively high carbon dioxide affinity (75). This method could also help wean some patients from mechanical ventilation and free other patients from tracheal intubation.

Future of Renal Dialysis

Research to prevent and reverse renal failure holds potential to reduce chronic renal failure and deaths from acute renal failure, both of which are prevalent among elderly people.[4]

As discussed in chapter 7, dialysis is an empirical therapy, meaning that treatment is determined by observing results in the individual patient rather than based on an understanding of the basic physiological mechanisms. Improvements in dialysis (or the development of an implantable artificial kidney) require basic physiological research. Researchers will be severely limited in devising new technologies until they identify specific parameters of ideal renal clearance. For example, the ideal clearance of urea is not known. Whether urea clearance is even an appropriate marker for adequate removal of other toxic substances is a subject of debate. Some experts believe the "middle molecules"[5] are the substances responsible for the symptoms of the uremic state and should be the focus of filtration efforts, although the identification and toxicology of these substances have not been established (77).

Improvements in conventional dialysis treatment will most likely be in these areas:

- devices and parts of the dialysis apparatus (e.g., dialyzers and catheters) to improve efficacy or reduce complications;
- supplemental or adjunct therapies (e.g., adsorbents or anticoagulants), also to improve efficacy and reduce complications; and
- the use of designs and techniques to enhance patient independence and mobility (e.g., CAPD, home dialysis, and miniaturization of apparatus).

Related technologies, such as plasma exchange and hemoperfusion, hold promise for arresting the progression of renal disease as well as for treating other diseases. Plasma exchange has been cited for use in a range of conditions, but proof of its efficacy is still needed (48). For instance, the majority of references on plasma exchange treatment are case reports, without any systematic or convincing evidence such as data from controlled studies or clinical trials.

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[4] Mortality from acute renal failure in patients over age 70 currently approaches 80 percent (28)

[5] While hemodialysis is effective in removing small molecules, substances of higher molecular weight will not pass easily through the dialysis membrane. These so-called "middle molecules" are thought to be uremic toxins and causes of dialysis complications.

A spectrum of technologies exists for the detoxification of blood, most of which are variations of hemodialysis. Approaches to blood detoxification fall into two categories: extracorporeal and intracorporeal. Extracorporeal approaches, including hemodialysis, hemofiltration, hemoperfusion, and other techniques, are characterized by the circulation of blood outside the patient's body. The intracorporeal approaches, such as peritoneal dialysis, are characterized by action within the body; the blood does not leave the body, although wastes must be disposed outside the body.

Hemodialysis

New hemodialysis products are regularly introduced. Efforts have been directed toward developing supplemental and adjunct therapies used in dialysis, scaled down dialysis equipment for patient convenience, and, ultimately, a wearable artificial kidney.

Adsorbents.—Adsorbents are used to regenerate and permit the reuse of dialysate and hemofiltrate. This controversial practice would not be possible without adsorbents. They are also an important supplemental therapy for dialysis and are especially important for the development of a compact artificial kidney system.

One example, the Redy adsorbent system, operates by enzymatic decomposition of urea by urease and adsorption of ammonium by zirconium phosphate. Creatinine, uric acid, and middle molecules are removed by activated charcoal (48). The Redy system can also be used for hemoperfusion, therapeutic hemapheresis, and as a dialysis monitor (14).

The oral administration of adsorbents is also used as a supplemental therapy for dialysis patients. A new combination of oxystarch (dialdehyde starch) and activated charcoal administered orally has proven effective as a supplemental therapy to dialysis (48). The oxystarch combines with urea or ammonium and the activated charcoal can adsorb creatinine, uric acid, and certain other middle molecules. Oral adsorbents must be coated to prevent damage to the patient's intestinal mucosa and decreased efficiency due to competitive adsorption of substances in the bowel tract. Because the major problems accompanying dialysis in elderly patients are poor blood access and an unstable cardiovascular condition caused by the strain of extracorporeal circulation, oral administration of adsorbents could be particularly beneficial because they could reduce or even eliminate the need for hemodialysis.

Membranes.—Semipermeable membranes are the surfaces across which the diffusion of dialysis occurs. One goal in the development of new membranes is improved biocompatibility. The majority of membranes developed since the early 1970s have been modified cellulosics or other synthetic materials. The older cellulosic membranes have been associated with complement activation,[5] and may be responsible for the high incidence and prevalence of infection in hemodialysis patients. Newer membranes show improved biocompatibility, i.e., less reduction of blood cell counts (especially white blood cells), and lower complement activation. Also, dialysis with a new synthetic membrane can be performed without anticoagulants (61). Most recently, a membrane (polysulfone) with a high protein permeability has been found to lessen the complications of chronic dialysis (62). Despite the numerous studies in this field, exact parameters of overall biocompatibility in blood purification systems are not well established.

Anticoagulants.—The use of an anticoagulant, usually heparin, is necessary during dialysis to prevent blood clots. However, chronic dialysis patients who use heparin regularly may suffer adverse effects on complement activation (81), platelet function change (82), lipid metabolism (22), and bone metabolism (48). Recently, new anticoagulants have been used to replace heparin, and dialysis has even been attempted without any anticoagulant. Although these alternatives are still experimental and have disadvantages (e.g., chemical instability, vasodilatory side effects), new drugs may make it possible to minimize or eliminate the use of heparin.

Dialysate.—Repeated exposure of the blood to dialysate is a problem because of chronic toxicity and unproven biocompatibility. Strategies to reduce dialysate-associated side effects include using a new buffer, quality control of dialysate to eliminate trace elements, and the reduction of the volume of dialysate per administration. For instance, a bicarbonate buffer results in less hemodynamic instability and other metabolic changes (49). Since dialysis systems are incapable of preventing the toxicity caused by trace elements combining with serum proteins, other means must be devised, such as agents capable of combining with and removing trace elements like aluminum, magnesium, and zinc, to prevent chronic toxicity (25,44,46). Also, dimethylnitrosamine, a known precarcinogen, has been reported in dialysate water; this may play a role in the increased incidence of malignant tumors in the dialysis population (50). Finally, a reduction in the volume of dialysate used per treatment would result in less cumulative exposure and could minimize the complications of such use.

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[5] *Complement* is a constituent of normal (nonimmune) serum that is required in addition to a specific antibody to cause the immune destruction of red blood cells and of certain bacteria. Complement consists of at least 17 proteins, which form a membrane attack complex. *Complement activation* plays a role in the induction of inflammation, various aspects of immunological defense, and in the pathogenesis of various immunologically mediated diseases (68).

Portable or Wearable Dialysis Systems.—Several methods to make dialysis more compact, and thus improve mobility and facilitate travel, are under investigation. For instance, some portable dialysis systems have been developed. One is a wearable artificial kidney, the WAK-III, consisting of a pumping section and an 18-liter reservoir, that was developed by investigators at Junken Co. (Japan) and the University of Utah. The large reservoir is, however, a problem for portability. Investigators at the University of Tokyo have been working on a more compact version, made possible by incorporating an adsorbent system to recycle the dialysate. Combined with pump sections, battery, and reservoir, this system weighs approximately 20 pounds. Another, lighter (10 pound) variation on the same system has been developed at the University of Tokyo. This simplified system, which is still in the preclinical stages, includes urea adsorbent, charcoal, ion-exchanger, and pump sections (48).

Another wearable continuous dialysis system is being developed by Research Development Systems of Pasadena, CA. Although animal trials have not yet begun, most of the components for the system exist. The proposed system would use 120 inches of dialysate tubing, holding 90 milliliters of blood outside the body at any given time. The system would weigh about 5 pounds and would be held by a holster under one arm. By continuously dialyzing blood, the system should avoid the discomfort associated with the more rapid cleansing of blood that occurs in traditional hemodialysis (39).

Continuous Arteriovenous Hemofiltration

Continuous arteriovenous hemofiltration (CAVH) utilizes water permeable membranes to remove excess fluids in acute renal failure. A hemofilter with a small surface area, small volume, and minimum circuit length are required to prevent straining the heart. Hemofiltration may be performed using the patient's own blood pressure without a blood pump. This allows for hemodynamically stable withdrawal of excess fluid without the use of elaborate extracorporeal circuits (66). (This method may also be used to provide nutritional support (58).) It may be especially appropriate for elderly patients, who are at added risk of developing multiorgan failure and often suffer nutritional, metabolic, acid-base, electrolyte, or hemodynamic abnormalities.

Continuous Ambulatory Peritoneal Dialysis

The most important complication associated with continuous ambulatory peritoneal dialysis (CAPD) is peritonitis (see ch. 7). Two relatively new products demonstrate the innovative approaches being investigated to control CAPD complications. DuPont's Sterile Connection Device (SCD) automatically makes a sterile splice between an air-filled extension tube of the dialysate bag and the patient administration set—thus eliminating the need to aseptically spike into the port of the bag and reducing the risk of infection (9). Another device to control infection irradiates with ultraviolet light the critical connection between the solution container and transfer set immediately before spiking. It does not, however, eliminate the need for aseptic practice (85).

Anemia Treatments

Practically all chronic dialysis patients eventually suffer from red blood cell anemias, requiring frequent blood or red blood cell transfusions. The anemias stem from the kidneys' inability to make erythropoietin, a hormone that controls the production of red blood cells by the bone marrow (21). Erythropoietin can now be mass-produced by genetic engineering. Patients receiving regular injections of the hormone need fewer blood tranfusions and have more energy (6).

Future of Nutritional Support

Nutritional support is used to provide necessary nutrients and fluids to patients who are unable for a variety of reasons to take in, digest, or absorb adequate amounts of food or fluids (see ch. 8). Receiving nutritional support, however, can be an uncomfortable experience for patients. Research on technology for enteral nutrition focuses on new materials to make feeding tubes more pliable, durable, and compatible with the body's own tissues and the composition of nutritional support formulas. Innovations for parenteral nutrition are devices designed to minimize patient discomfort and complications, especially the so-called "tunnel" infections associated with the use of catheters in long-term care.

Parenteral Nutrition

Even patients receiving meticulous care may develop complications associated with catheters, including thrombus formation,[7] structural failure, and infection. Research efforts are focused on reducing complications associated with the catheters used for parenteral administration. For example, the standard polyethylene or silicone catheters in widespread use for total parenteral nutrition (TPN) have been associated with a 33 percent incidence of thrombus formation (34,56). To alleviate such complications, researchers hope to identify better biocompatible materials for the catheters. Preliminary evidence from clinical investigation shows that the incidence of thrombophlebitis is lower with a polyurethane catheter than with a silicone catheter (56). Another trial of polyurethane catheters showed no evidence of venous thrombosis (up to 820 days) without the administration of any heparin (33). Another strategy may be to coat catheters with antimicrobial agents (35).

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[7] A *thrombus* is essentially a blood clot, but is differentiated by the fact that a thrombus frequently causes vascular obstruction at the point of its formation, while a blood clot is more likely to be carried through the circulatory system.

Vascular Access Devices.—Other attempts to minimize complications associated with TPN have focused on developing implanted vascular access devices, which consist of a self-sealing silicone rubber septum encased in a port made of metal or plastic attached to a silicone catheter. Fluids, drugs, and blood can be administered into this port system by a simple needle puncture through the skin into the port. These systems could lessen the potential for infection and be more esthetically acceptable to patients. Also, the need for dressing changes is eliminated (48).

Infusion Pumps.—Computerized infusion pumps represent a dramatic improvement over gravity-flow procedures in the accuracy of infusion volume (see ch. 8), but could be improved. Some factors that may require additional attention include: range and accuracy, flow rate continuity, operation during transport, resistance to tampering and accidents, memory functions, alarm disable, battery life, electrical safety, electromagnetic interference, quiet operation, ease of use, and servicing (48).

Enteral Nutrition

Research on equipment for enteral feeding includes two main areas. Some work is focused on the actual tubes used to deliver formula. Using the smallest tube that will allow for passage of the formula maximizes patient comfort and tolerance. Other research focuses on the electronic enteral pumps now being used to maintain an accurate infusion rate and facilitate delivery of the viscous solution by applying continuous positive pressure.

Enteral formulas specific to the nutritional needs of elderly people are not available. Nutritional support specialists and industry representatives differ in their views about whether such formulas could or should be developed. The numerous commercially available premixed enteral formulas differ in osmolarity, digestibility, caloric density, lactose content, viscosity, residue, fat content, taste, and cost (48). Customization of enteral formulas according to individual needs would be ideal; however, the capability of many long-term care facilities to accurately assess an individual's nutritional needs and provide the appropriate formula lags far behind this ideal, primarily because they lack trained personnel (see ch. 8).

Some research is looking at nutritional support as a way to treat diseases, not simply to correct malnutrition. For instance, evidence shows that dietary manipulation can substantially slow the loss of renal function at early and late stages of chronic renal disease (60). Adjustment of fat intake can reduce the retention of carbon dioxide, a problem for some ventilation patients. Rheumatoid arthritis, diabetes, chronic obesity, and heart disease may be ameliorated by nutritional therapy (45).

Extracorporeal Blood Treatment

Some extracorporeal blood treatment technologies may have applications for improving the nutritional status of very ill elderly patients by means of immunometabolic support. For instance, therapeutic hemapheresis, especially on-line plasma treatment with the return of essential nutrients, is an approach to preserving nutritional and immunological homeostasis. The treatment may be used to filter off the pathological macromolecules associated with certain diseases and then to add essential nutrients to the plasma being returned to the patient. Certain plasma treatment technologies result in the discarding of a portion of the plasma, which may result in further nutritional depletion in patients whose nutritional status may already be compromised; therefore, use of extracorporeal technologies must be considered carefully (48).

Future of Antibiotic Therapy

New strategies to cope with life-threatening infections span a variety of research areas, including new drugs and techniques for developing drugs, the metabolism of drugs in elderly patients, drug delivery systems, and manipulation of the immune system.

Antibiotic Development

More than three dozen new antibacterials will be approved by the FDA by 1991, according to one industry report (80). The development of new drugs takes advantage of new manufacturing opportunities, such as genetic engineering, computer-assisted design of pharmaceuticals, and, potentially, pharmaceutical manufacturing in space. Ongoing antibiotic development will quicken as the pharmaceutical industry masters new biotechnology techniques. New or next-generation antibiotics could significantly improve antibiotic therapy, but early information on the development of new antibiotics is not easy to obtain because of the proprietary nature of most pharmaceutical research and development.

Antibiotics are developed by screening compounds from natural sources, often soil molds, and often chemically modifying these substances. Such modification can broaden or narrow the antibiotic's range of activity (80). The most significant contribution of new antibiotics may be in conquering bacteria that are resistant to the usual drug of choice (e.g., penicillin, tetracycline).

Two recently developed antibiotics can act against a wide spectrum of bacteria, including many infections that are resistant to other antibiotics. Primaxin, developed by Merck, is especially useful against multiorganism infections and infections caused by bacteria that are resistant to other antibiotics (19). Aztreonam, recently approved by the FDA, acts against gram-negative bacteria, the cause of about half of all nosocomial infections. Because Aztreonam does not induce bacterial synthesis of a particular enzyme, bacteria should be slow in developing resistance to this drug (24).

Along with new drugs, better application of existing drugs can be expected in the coming years. Recent medical literature highlights the lack of complete information on the pharmacological effects of drugs in elderly people. Research to identify proper geriatric dosages and to eliminate, or at least reduce, adverse effects and toxicity is crucial to safe and effective treatment of infection in the elderly, particularly since compromised immune systems and polypharmacy are more likely in elderly patients (see ch. 9). Some progress may be made toward these problems with the development of computer programs to perform tasks such as checking new prescriptions for compatibility with other prescriptions or issuing prescription guidelines with age-adjusted dosages. One computer system under development, for example, constantly monitors indications for antibiotic therapy and reports its medical decisions to physicians, thus bringing potentially life-saving information to their attention (31).

Drug Delivery Systems

Traditional methods of introducing drugs into the body include oral, topical, nasal, intravenous, intramuscular, subcutaneous, and intrathecal (into the spinal column) administration. Certain drugs are only suitable for particular delivery methods. In recent years, considerable effort has been devoted to developing new technologies for drug delivery. Among the innovations that may be particularly important for elderly patients are sustained or timed-release drugs, targeted antibiotics (high local but low general levels), and monitoring systems that assure proper therapeutic levels of the drug in the bloodstream. More precise control over dose maintenance can reduce the toxicity and side effects associated with serial administration (very high immediately after introduction, decreasing over time). Sustained- or automatic-release drugs may also protect against forgotten medication and dosage mistakes. Directed delivery systems are especially important for treating localized infections and controlling the administration of toxic drugs.

The emphasis on alternate-site care will fuel demand for alternate drug delivery systems. Oral and other self-administered drugs and timed-release drugs often reduce the need for conventional nursing and physician services, thus lowering personnel costs and increasing opportunities for nonhospital care. Since drugs have differing characteristics and patients have differing medication needs, personal preferences, treatment sites, degrees of independence, and other needs, alternatives to traditional drug delivery systems will affect quality of care.

Some drug delivery systems under development will provide feedback, such as information on the location and level of drugs in the body, so that treatment may be modified as necessary. Other feedback systems automatically regulate the release of a drug by responding to environmental stimuli. Some delivery systems are described in table C-2. It is not yet clear which systems may come to play a useful role in the treatment of life-threatening infections in elderly people.

Intravenous Antibiotic Administration.—Intravenous (IV) administration of antibiotics allows either continuous or intermittent delivery of antibiotics directly into the bloodstream. Although electrically powered and electronically controlled infusion pumps have allowed better control over the rate of delivery, other improvements are needed to reduce the complications of intravenous administration. The most frequent complication of IV therapy is infection as a direct result of the surgical insertion of a catheter, because the opening through the skin provides easy access for bacteria. The most imminent improvements are modified vascular access devices designed to eliminate infection.

"Microscopic" Delivery Systems.—Other drug delivery systems operate on a microscopic level—i.e., drugs are delivered by grouping or repackaging drug molecules. One theoretical approach is to develop *polymeric forms* of individual drugs, which are more stable, less toxic, and capable of slow release of active units. However, research to synthesize useful polymeric drugs (including antibiotics) has been unsuccessful so far (48).

A more feasible approach to drug delivery on the molecular level is encapsulation, a process in which pharmaceuticals are packaged inside a biodegradable

Table C-2.—Drug Delivery Systems Under Development

Type of system	Primary advantages	Description	Comments
Implantable infusion pump	Sustained constant release	One model utilizes a chemical pump—a fluorocarbon inside the device vaporizes and exerts pressure on a "tiny bellows" that drives the drug out	Single-use pumps; require surgical implantation and removal; unresponsive to changes in environment; not yet used for antibiotic delivery
Oral osmotic "pill" pump	Sustained release; passes naturally through body in about 24 hours	Consists of a drug-filled core, surrounded by a semipermeable polymer membrane which lets gastric juice in. As the fluid enters, the pressure inside the membrane builds, and the drug is pumped out evenly through a tiny laser-drilled hole in the membrane	Successfully tested in clinical trials; not yet used for antibiotic delivery, athough tested on several other drugs
Implantable osmotic pump	Sustained, local release	Relies on membrane-controlled osmosis for drug delivery	Successfully tested in animals for antibiotic delivery; requires surgical implantation and removal; significant technical questions remain unanswered
Biodegradable implant	Sustained, local release	One type of implant utilizes a biocompatible plastic, called Polyhydroxybutyrate (PHB), which is created by bacteria	Some capable of drug release for over 60 days; does not require removal; obstacle often cost-effective production of implant materials
Ferrofluids	Directed delivery	Biocompatible magnetic shavings could be suspended in drugs, then the drugs could be injected and then directed to and retained at specific treatment sites by an externally applied magnetic field	Still in early research stages; originally developed by NASA; not yet applied to drug (or antibiotic) delivery
Self-regulated, chemically modulated systems	Automatic regulation of rate of release	Releases drugs in response to a particular environmental stimulus	Experimental systems have little therapeutic relevance so far; a practical application might be one which released penicillin in response to the bacteria in the bloodstream

SOURCES: Biomedical Business International, *Drug Delivery Systems, Technology, Companies and Market*, Report #7016 (Tustin, CA: April 1985).
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microcapsule, either for sustained-release or for local concentration of the drug. The process also protects unstable molecules from the immediate environment, protects body tissue from certain drugs, inhibits toxicity and anaphylaxis by avoiding large doses, and masks unpleasant tastes and odors. However, scaling up production methods for industrial volumes can present a variety of problems. Such difficulties can result from sensitive environmental requirements for production or prohibitively expensive reagants (64). Three of the materials being investigated for drug encapsulation are described in box C-3.

A critical factor in the treatment of infection in elderly people is the natural change in the immune system associated with aging. In addition, the immune response in ill elderly people may differ considerably from that of healthy elderly people. Therefore, optimal treatment would require a good understanding of both normal, age-associated changes and abnormal, disease-related changes, and the ability to compensate for them. *Infusion* of fresh leukocytes or lymphocytes has been attempted, as well as the use of sophisticated sorting technologies to separate and infuse only certain subsets of cells (e.g., T-cells or B-cells) (48). *Immunoactivation* refers to the intentional manipulation of processes of the immune system to stimulate a specific immune response, such as complement activation or interferon therapy. *Immunoadsorption* refers to extracorporeal plasma treatment with adsorbents to remove abnormal immunocomplexes. Although these techniques are still experimental, investigators hope that their use will someday enhance the effectiveness of treatment for infection in immunocompromised patients.

Technologies To Diagnose Infection

Treatment decisions for infections in elderly people are often complicated by compromised immune function, the presence of comorbidities, and multiple infections. In all cases, good treatment depends on rapid and accurate diagnosis. New biotechnologies, such as monoclonal antibodies and DNA probes, present a major opportunity to improve diagnostic methods because of their ability to recognize infectious agents with a high degree of specificity. If biotechnology is successfully merged with sophisticated computer scanners, rapid diagnoses should be possible through the analysis of blood or other body fluids, thereby allowing earlier selection of therapy (30).

In certain infections, identifying the pathogenic organism is the easy part. More difficult is locating the site of the infection to determine the appropriate course of treatment. But physicians do not yet have the means of locating all infections. The example of single-dose antibiotic treatment for urinary tract infections described in box C-4 demonstrates the nature of the diagnostic problem and efforts toward its resolution.

Box C-3.—Materials Under Investigation for Drug Encapsulation

- **Liposomes** can hold drugs within their lipid-molecule membranes. Some successes in animal tests have been reported in the use of liposomal anti-microbials for the treatment of fungal infections. Advantages include increased permeability of the blood-brain barrier, reduced toxicity, and increased efficacy (48). Despite their promise, liposomes are limited in their potential because only water-soluble drugs can be encased—otherwise the liposome will take up water and burst (76).
- **Monolayer membrane envelopes** are injectable droplets created by encasing drugs within membrane envelopes made up of natural components of human cellular membranes. The capsules are large enough to contain drugs and to remain localized where injected, but not large enough to obstruct blood vessels. The membrane envelopes differ from liposomes in that their membranes allow the slow, sustained release of lipid-soluble (not water-soluble) drugs. At present, the membrane envelopes are being tested for the post-operative administration of local anesthetics at the point of incision; other applications may be in cancer chemotherapy, nerve blocks for dentistry, and sustained antidepressant administration. Developers hypothesize that up to one-third of the drugs listed in the *Physicians' Desk Reference* are candidates for this system because of their relative lipid solubility (76). The capacity for localized placement is attractive for the treatment of some infections.
- **Amino acid microcapsules** contain genetically engineered cells that repeatedly produce a desired substance (e.g., insulin or antibodies). These "creator cells" are placed in an amino acid microcapsule, where they continue to produce the desired product. Finally, the microcapsules containing the "creator cells" are injected into the body where the products are released. The cycle of production and release of the byproduct continues after injection. In addition, the microcapsule is not rejected as a foreign body by the body's immune system because of its amino acid structure. The process has been successful in supplying all of the insulin needs of diabetic mice; it has not been tested for the production of antibodies (18).

Box C-4.—Single-Dose Antibiotics

Urinary tract infections (UTIs) are easily identified by a positive urine culture. However, current tests used to diagnose UTIs are incapable of differentiating between deep tissue and superficial mucosal infections because the test is only capable of identifying the organism. Further, the disposition of UTIs is very different in men and women. In women, UTIs are very common and the great majority of infections (about 80 percent) are superficial mucosal infections; only a small group are deep tissue infections (i.e., bacterial infection of the kidney). In contrast, the vast majority of UTIs in men are deep tissue infections (e.g., prostate) (73).

The significance of this diagnostic insufficiency is that the great majority of superficial mucosal infections respond to a single dose of antibiotics, but deep tissue infections require an extended course (4 to 6 weeks) of antibiotic treatment. Thus, "diagnosis" of deep tissue infections is really the use of an algorithmic approach that divides patients according to their response to a single-dose of antibiotics. The goal of current research is to devise an assay that can stratify patients into treatment groups (single-dose or extended course) at the time of their initial diagnosis. Such a test would prevent the expense and risk associated with long-term antibiotic treatment. One specific approach to the development of such a test involves examining bacterial virulence factors; it is believed that there are identifiable markers that are correlated with the likelihood of deep tissue infections (73).

Little research has been done specifically on elderly patients. UTIs are frequently asymptomatic in elderly patients. Some physicians contend that it is not necessary, and possibly even improper, to treat asymptomatic UTIs in elderly patients. It has been demonstrated that if asymptomatic UTIs are treated, and the infection fails to respond to the antibiotic, the patient in relapse may experience painful or uncomfortable symptoms, which previously were not exhibited. Thus, some question the wisdom of altering what seems to be a natural symbiosis (73).

Conclusion

Current research and development holds promise for improving both the quality of medical care and the quality of life for many patients dependent on life-sustaining technologies. Future developments could make treatments more effective, more comfortable, more portable, cheaper, and less invasive. These changes will occur as existing technologies are improved and new technologies are created. For some patients, however, improvements in the technologies may only serve to extend the period of pain and suffering caused by their underlying disease. The technologies themselves will not resolve the difficult dilemmas created by the advances of modern medical science. Thus, improvements in prognostic tools and decisionmaking are also needed.

Prevention of life-threatening diseases may be more effective at reducing the incidence of illness and premature death than incremental improvements in life-sustaining technologies. But prevention, even if broadly and successfully implemented, will not obviate life-sustaining technologies. If preventive measures for heart disease were widely implemented, for example, other life-threatening illnesses would become more common.

Widespread implementation of preventive strategies is always difficult. The strategies discussed for preventing heart disease, for instance, are inconsistent and confusing. Even more significant is the low level of motivation that many people have for preventive health behavior before they become ill. Strategies for secondary prevention, at the time of symptom onset, may thus be more feasible. As preventive strategies are developed, policymakers may need to make more explicit decisions about the relative commitment of resources to preventive programs.

The technologies described in this appendix are only examples of a wide range of R&D efforts that are underway. Many other technologies could have been included. Some potential technologies will never be clinically used, while others will soon become standard procedures. Each technology may eventually find different applications from those described here, and new developments will make possible technologies not yet imagined. Decisions made in the next few years by researchers, manufacturers, providers, patients, and policymakers will determine which technological developments become available in the next decade and how they are used.

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Appendix D

NRCBL International Directory of Bioethics Organizations

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Georgetown University
Washington, DC 20057
(202) 625-2383
(800) MED ETHX
Director: Doris Goldstein, M.L.S., M.A.

INTERNATIONAL DIRECTORY OF BIOETHICS ORGANIZATIONS
Compiled by
Robert C. Iosco

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Bioethics consists of the application of ethical reasoning to dilemmas in the biomedical or life sciences. This directory lists organizations that have a professed interest in the study of bioethics and serves as a resource for those who wish to pursue bioethical issues in more detail. The organizations listed represent a variety of types of programs.

The following list, which is current as of June 1987, is continually updated by the staff at the National Reference Center for Bioethics Literature:

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Center for Bioethics
St. Joseph Health System
440 South Batavia Street
Orange, CA 92668
Telephone: (714) 997-7690
Director: Sr. Corrine Bayley

Joint Program in Bioethics
Health Policy Program
School of Medicine
1326 Third Avenue
San Francisco, CA 94143
Telephone: (415) 666-3093
Director: Albert R. Jonsen, Ph.D.

Loma Linda University
Center for Christian Bioethics
Division of Religion
Loma Linda, CA 92350
Telephone: (714) 824-4956
Director: David Larson, Ph.D.

Program in Medical Ethics
Department of Medicine
Div. Pulmonary & Critical Care Medicine
UCLA School of Medicine
Los Angeles, CA 90024
Telephone: (213) 825-2371
Director: Leslie Steven Rothenberg, J.D.

Society for Bioethics Consultation
P.O. Box 10145
Berkeley, CA 94709
Telephone: (415) 486-0626
Director: John Golenski, S.J., Ed.D.

Pacific Institute for Biomedical Education
and Research
P.O. Box 1143
Solvang, CA 93463
Director: Teresa A. Takken, Ph.D.

COLORADO
Center for Applied Biomedical Ethics
Rose Medical Center
4566 East Ninth Avenue
Denver, CO 80220
Telephone: (303) 320-2895
Director: Fredrick R. Abrams, M.D.

CONNECTICUT
Pope John Paul II Bioethics Center
Holy Apostles College and Seminary
Cromwell, CT 06416
Telephone: (203) 635-5311
Director: Fr. Francis Lescoe

DELAWARE
Center for Science and Culture
University of Delaware
28 West Delaware Avenue
Newark, DE 19711
Telephone: (302) 738-8194
Director: Paul T. Durbin, Ph.D.

DISTRICT OF COLUMBIA
Biomedical Ethics Board—U.S. Congress
c/o Senator Albert Gore, Jr.
United States Senate
Washington, DC 20510
Telephone: (202) 224-4955

Center for Bioethics
Kennedy Institute of Ethics
Georgetown University
Washington, DC 20057
Telephone: (202) 625-2383
(After fall 1987: (202) 687-3885)
Director: LeRoy Walters, Ph.D.

Center for Law and Religious Traditions
Catholic University Law School
Washington, DC 20064
Telephone: (202) 635-5140
Director: George P. Smith, J.D.

Division of Health and Humanities
School of Medicine, Georgetown University
3900 Reservoir Rd., N.W.
Washington, DC 20007
Telephone: (202) 625-2282
Director: Warren T. Reich, S.T.D.

FLORIDA
Bioethics Institute at St. Francis Hospital
250 West 63rd St.
Miami Beach, FL 33141
Telephone: (305) 868-5000
Director: Rev. James J. McCartney, OSA, Ph.D.

ILLINOIS
Center for the Study of Ethics in the Professions
Illinois Institute of Technology
Chicago, IL 60616
Telephone: (312) 567-6913
Director: Martin Pimsler

Center for the Study of Medical Ethics
Pritzker School of Medicine
Box 72—University of Chicago
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Telephone: (312) 962-1453
Director: Mark Siegler, M.D.

Council on Ethical & Judicial Affairs of
American Medical Association
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Chicago, IL 60610
Telephone: (312) 645-5000
Director: William J. Tabor

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Chicago, IL 60611
Telephone: (312) 508-2297
Director: Thomas Wren

Medical Humanities Program
Loyola Medical Center
2160 South First Avenue
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Telephone: (312) 531-3433
Director: David C. Thomasma

The Park Ridge Center
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Park Ridge, IL 60068
Telephone: (312) 696-6399
Director: Martin E. Marty, President

INDIANA
Human Genetics & Bioethics Education Lab
College of Sciences and Humanities
Ball State University
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Telephone: (317) 285-8840
Director: Dr. Jon R. Hendrix

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Director: George J. Annas, J.D.

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Harvard University
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Boston, MA 02115
Telephone: (617) 732-1065
Director: William J. Curran, J.D., LL.M.

Pope John XXIII Medical-Moral Research & Education Center
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Telephone: (617) 848-6965
Director: Fr. William M. Gallagher, Pres.

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University of Minnesota
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Interim Director: Diane Bartels

Minnesota Network for Institutional Ethics Committees
c/o Minnesota Hospital Association
2221 University Avenue, S.E.
Suite 425
Minneapolis, MN 55414
Telephone: (612) 331-5571
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American Nurses Association
2420 Pershing Road
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Telephone: (816) 474-5720
Director: Kathleen M. Sward

Division of Health Care Theology and Ethics
Catholic Health Association
4455 Woodson Road
St. Louis, MO 63134
Telephone: (314) 427-2500
Director: Laurence J. O'Connell, PH.D., S.T.D.

Midwest Center for Bioethics
1200 East 104th Street
Suite 217
Kansas City, MO 64131
Telephone: (816) 942-1992
Director: Hans Uffelmann, Ph.D.

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The Ethics Institute
Dartmouth College
Hanover, NH 03755
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NEW JERSEY

Commission on Legal & Ethical Problems in the Delivery of Health Care
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Trenton, NJ 08625
Telephone: (609) 393-0730
Director: Connie Myers

NEW YORK

Center for Study of Society & Medicine
Columbia University
College of Physicians & Surgeons
630 West 168th Street
New York, NY 10032
Telephone: (212) 305-4184
Director: David Rothman, Ph.D.

The Hastings Center
Institute of Society, Ethics, and the Life Sciences
255 Elm Road
Briarcliff Manor
New York, NY 10510
Telephone: (914) 762-8500
Director: Daniel Callahan, Ph.D.

Institute on Human Values in Medical Ethics
Elmwood Hall
New York Medical College
Valhalla, NY 10595
Telephone: (914) 993-4000
Director: Samuel H. Rubin, M.D.

Manhattan College Center for Professional Ethics
Manhattan College Parkway
Riverdale, NY 10471
Telephone: (212) 920-0114
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Rennes, France 35043
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Service de chirurgie
Toulouse, France 31054
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des aff. medical
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Paris, France 75004
Telephone: (1) 277-11-22
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Comite d'ethique du CHU de Nice
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Nice, France 06002
Director: A. Ollier, Secretaire

Comite d'ethique du CHU de Rouen
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Boite postale 97
St. Etienne du Rouvray 76800 France
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Comite d'ethique du groupe de recherche
sur le medicament
4, rue Blaise Pascal
Strasbourg, France 67070
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Comite d'ethique medicale
24, avenue du Colonel Schuller
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18, rue Porte-Dijeaux
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GERMANY, EAST

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ITALY
Centro di Bioetica/Societa di letture
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Genoa, Italy
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Appendix E

NIH Workshop Summary: Withholding and Withdrawing Mechanical Ventilation

In October 1985, a workshop entitled "Withholding and Withdrawing Mechanical Ventilation" was sponsored by the National Heart, Lung, and Blood Institute, American Association of Critical-Care Nurses, American Association for Respiratory Care, American College of Chest Physicians, American Thoracic Society, and the Puritan Bennett Foundation. The 3-day meeting brought together clinicians, researchers, lawyers, ethicists, and others.[1]

Proceedings of the workshop, as summarized in an article in *American Review of Respiratory Diseases*, are reproduced here.[2] They focus on the difficulty of arriving at optimal treatment decisions and the use of institutional policies and other means to help patients and caregivers make better-informed decisions regarding the use of mechanical ventilation.

Introduction

The second half of the 20th century has seen a movement toward shared decisionmaking between physician and patient in medical care. This welcome trend has causes that include rapid technological advances, a more health-conscious public, better understanding of the limitations of health care, and the emergence of less autocratic health-care providers. However, these developments have been accompanied by a new way of dying in that the last days of life are often spent in an expensive hospital environment in which the patient, through mental incompetence or physical incapacity, is unable to make decisions about personal medical care.

The widespread use of mechanical ventilation has occurred in the last two decades. Mechanical ventilation first became available outside the operating room and recovery room in the mid-1960s. At that time each major hospital usually had one intensive care unit, and patients were admitted based on the judgment of the director and the family physician. This resource was applied only to patients who seemed likely to recover. Today the situation has changed, although mechanical ventilation remains only supportive, until the patient's underlying disorder of the central nervous system, neuromusculature, or lung improves spontaneously or responds to specific therapy. Every hospital now has the capacity to institute mechanical ventilation, and paramedical personnel often initiate the process by manual ventilation in the home as part of cardiopulmonary resuscitation. Endotracheal intubation and mechanical ventilation are frequently instituted by medical personnel who have little previous knowledge of the patient, and since this therapy is immediately life sustaining, it is often impossible to contact the family, surrogate, or personal physician prior to its initiation. As a result, the ability to prolong life or the dying process is no longer in the hands of a few, select medical personnel but is available in every medical facility where emergency medicine is practiced and in most mobile life support units. This capability, although beneficial in many cases, carries with it the potential for overwhelming emotional hardship, agonizing pain, and devastating financial cost for the patient and the patient's family.

Prognosticating Outcome in the Severely Ill

Decisionmaking about life-sustaining therapy is complicated by our inability to prognosticate outcome in the severely ill or injured person. Subgroups of patients with particularly poor prognoses who undergo mechanical ventilation have been difficult to identify. For instance, it is common knowledge that severely immunosuppressed individuals and those with liver failure who develop acute respiratory failure have a poor prognosis, but these perceptions are based on limited anecdotal evidence from a few medical centers. In this regard, physiologic scoring systems such as the APACHE II scheme may prove useful to categorize severity of illness and help predict outcome (1). The most useful prognostic data have been obtained on patients with coma (2). In this large series, less than 2 percent of patients with nontraumatic, nondrug-induced coma, who lacked at least two of corneal, pupillary, and oculovestibular responses within hours of the onset of coma, ever regained independent function. However, most patients who receive mechanical ventilation have less predictable outcomes.

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[2] Reproduced from "NIH Workshop Summary: Withholding and Withdrawing Mechanical Ventilation," *American Review of Respiratory Diseases* 134: 1327-1330, 1986, used with permission.

The Persistent Vegetative State

Decisionmaking about mechanical ventilation often concerns patients in a persistent vegetative state, since many patients in this state are maintained on ventilators. These individuals are not brain dead, but rather appear to be awake with open eyes and sleep-wake cycles. They can be seen to follow movement with their eyes and sometimes will swallow food placed in their mouths. However, they neither speak, follow commands, nor show cognitive awareness of themselves or their surroundings. This state may rapidly follow coma, and if it persists for more than a few weeks, usually indicates an extremely poor chance for recovery of independent function (3). Unfortunately, the onset of this state is difficult to predict and its outcome only becomes apparent after weeks of therapy.

For most patients who are supported by mechanical ventilation, the prognosis is less clear. Furthermore, for some individuals with more favorable prognoses, mechanical ventilation and other intensive medical treatment may be perceived as so burdensome that it is declined by the patient or the surrogate. In each of these circumstances, health care professionals are increasingly called on to provide counsel and advice about withholding or withdrawing mechanical ventilation and other life-sustaining therapy. What are the elements involved in making and implementing these decisions? Can high-quality patient care be maintained? Detailed answers to these questions were orginally given in a publication of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research entitled "Deciding To Forego Life-Sustaining Treatment" (4). In the following sections we describe some procedures for making and implementing these decisions, and we outline topics that require further study and development.

Withholding and Withdrawing Therapy

Mechanical ventilation is an example of life-sustaining therapy because it substitutes for an essential physiologic process that is not functioning properly. However, the simplest supportive measures can place undesirable and intolerable burdens on the dying or irreversibly incapacitated patient by unnecessarily prolonging suffering. In such a patient, intravenous feeding, antibiotic therapy, and even enteral feeding are now regarded by many as appropriate for withdrawal when the burden of the treatment outweighs any benefit the patient can derive. It has become increasingly acceptable to contrast the benefit and the burden of specific treatment rather than regard it as ordinary or extraordinary (5). In this way an extremely painful or invasive treatment might be advocated if it were likely to result in significant improvement, but even a minimally supportive treatment might not be condoned if the prognosis were dismal (6,7).

With mechanical ventilation, however, we deal with immediacy, literally with the breath of life. Because of this immediacy we are often reluctant to withhold this treatment, and we are even more ambiguous about withdrawing mechanical ventilation. Our reluctance and ambiguity have practical reasons. First, the decision to withdraw is more often made by a surrogate, whereas the decision to withhold is more likely to be made by the patient. Surrogate decisionmaking is less precise. It is more likely to be tediously scrutinized by the press, the courts, and other parties. Decisions to withdraw take longer to implement; the family and usually the entire intensive care unit team must be prepared more carefully. Finally, withdrawing therapy is humiliating to many physicians. Withholding therapy always leaves a doubt about whether the therapy might have worked, but withdrawing is the public admission that therapy has failed, which may be difficult for the treating physician to accept. Withdrawal of mechanical ventilation is particularly poignant since it often leads quickly to death. However, these differences are practical and emotional. There are no ethical or legal differences between withdrawing and withholding mechanical ventilation.

Decisions to withhold or withdraw mechanical ventilation must be based on an essentially similar decisionmaking process. The decision to withhold generally deserves more scrutiny than the decision to withdraw, but rarely gets it. A rationale for withholding therapy is also adequate for withdrawing it. Furthermore, the act of withdrawal is generally a more informed act because the therapy has been initiated and shown not to work. It is clear in medicine that a therapy should be discontinued when it is not working or is so burdensome to the patient that it cannot be tolerated. Finally, the decision to withdraw mechanical ventilation from a dying or irreversibly incapacitated patient cannot be said to cause death. It merely allows death to occur from whatever necessitated mechanical ventilation in the first place (4).

That the patient can refuse treatment of any kind is regarded as a fundamental legal right in our society. It is relatively easy to respect the decision of the competent patient who can understand the prognosis, is informed of the therapeutic alternatives, and voluntarily makes a decision regarding medical care. In cases where a physician cannot in conscience comply with the decision, the patient's care should be transferred to another physician. However, decisionmaking for the person who is not legally dead but is incompetent or incapacitated becomes more difficult.

In recent years two powerful instruments have emerged that allow the individual more control in circumstances when competence or physical capacity may be compromised. These instruments are the living will (8) and the durable power of attorney (9,10). The living will is a written and witnessed document that expresses the patient's desires about medical care in the event of incompetence or incapacity. The living will generally cannot specify the exact circumstances under which an individual would want therapy withheld, although health care professionals have in some instances prepared very detailed living wills for themselves. Being an advance directive it lacks the moral force of contemporaneous decisionmaking by the patient. A physician might consider it inappropriate for fulfill the directive of a living will because its general language does not reflect a full understanding of the specific treatment decision to be made and the benefit that might be obtained. It should be noted, however, that no civil or criminal action has been successfully brought against a practitioner for following the instructions of a living will.

In an effort to codify the concepts of the living will, currently 35 States and the District of Columbia have enacted laws related to a patient's legal right to refuse medical treatment. Even in States which have no legislation, living wills are being recognized as an indication of the patient's intentions, including the right to refuse treatment. These laws are widely known as natural death acts, and although they give some legal foundation to the concept of the living will, they also raise as many questions as they answer (11,12). Perhaps most importantly, few of these laws provide for appointment of a proxy decisionmaker in the event of a patient's incompetence or incapacity. In response to this need, the concept of durable power of attorney is being increasingly used to provide for a surrogate decisionmaker. The word "durable" means that the authority of the surrogate continues to be effective when the patient becomes incompetent or incapacitated. Unlike the common law nondurable power of attorney, the surrogate has authority when it is most needed. This concept is legally accepted in all States with the exception of the District of Columbia, which has no enabling legislation. It is a somewhat stronger idea than the living will because it allows for more flexibility in the decisionmaking process in response to the circumstances that affect the patient. Previously, durable power of attorney was used more often to protect an individual's business and financial interests, and consequently the application of this instrument to decisionmaking on health care matters is relatively new. Living wills and durable power of attorney generally apply only in the event of the patient's incompetence and each is easily revokable. It must be recognized that in each State there will be differences in the applicability of laws relating to durable power of attorney and living wills. More uniformity across the States in regard to these acts is needed (see proposed "Uniform Rights of the Terminally Ill Act" by the National Conference of Commissioners on Uniform State Laws, 645 N. Michigan Avenue, Suite 510, Chicago, IL 60611, (312) 321-9710).

Making and Implementing the Decision To Withhold Cardiopulmonary Resuscitation and Mechanical Ventilation

The decision to withhold cardiopulmonary resuscitation and mechanical ventilation is not a trivial one and should not be rushed by the caregiver. In many instances a minimum of several discussions with the patient, family, and other interested parties over a few days is necessary. For the competent patient or the incompetent patient's legally recognized surrogate, the decision must be *voluntary* after full *disclosure* about *prognosis* and *therapeutic alternatives*. The caregiver may make medical recommendations but must not impose personal opinions about quality of life on the decisionmaker. In all instances it is desirable that there be unanimity about the decision among family and other interested parties. The need for unanimity becomes crucial when the patient is incompetent and there is no legally authorized surrogate, since unhappy family members or caregivers who were not included in the decisionmaking process can unnecessarily complicate it. When irreconcilable differences exist between parties interested in this decisionmaking process, introduction of a *facilitator* in the form of a clergy member or ethicist can be extremely useful.

While competent patients are legally entitled to refuse any treatment, including those that sustain life (such as mechanical ventilation), physicians serve patients best by maintaining a presumption in favor of sustaining life and rendering optimal treatment. In other words, when in doubt, the physician should err in favor of sustaining the life of a patient for whom there may be a question of competency or other problems that cannot be easily resolved. In the case of an incompetent patient, treatment could be revoked later by a recognized surrogate. This revocation could be based on specific instructions from the patient or on the patient's best interests if no clear prior directive had been given to the surrogate.

Given the desire of many patients to take an active role in the decisionmaking processes related to their health care, physicians and nurses should take the necessary time to discuss life-sustaining treatment with patients so that well-informed decisions about treatment can be made in advance. The attending physician, who presumably has established a prior relationship with the patient, should initiate these discussions, possibly in the presence of close family members, and most importantly before any emergent, life-sustaining intervention becomes necessary. The patient can best communicate this decision by making an explicit statement to the physician and at the same time executing a prior directive, such as durable power of attorney or a living will. Resolving the logistics of carrying out the directive falls on the patient, physician, hospital, and particularly, emergency room personnel. If possible, copies of prior directives should be made part of the patient's medical record. More readily available means to communicate a prior directive such as a necklace or bracelet, a microfilm chip attached to the driver's license, or similar identification should be widely available. Health care institutions have an obligation to establish clear procedures for communicating the existence of such a directive as well as providing for its implementation.

Patients, family members, and health care professionals are often uncomfortable discussing life-sustaining treatments such as cardiopulmonary resuscitation and mechanical ventilation when the patient is feeling well. Historically, medical and nursing education has provided little training in this area. The uncertainty of medical prognostication, as well as the reluctance of physicians and family members to accept responsibility for value judgments of this type also contribute to the uneasiness. Many patients, however, have definite opinions regarding cardiopulmonary resuscitation and mechanical ventilation and are willing to discuss these when asked. For example, in patients with a chronic illness such as advanced chronic obstructive pulmonary disease, which is likely to progress to the point where mechanical ventilation will be necessary to sustain life, open discussion among physician, patient, and family is essential. A second example is that of the healthy elderly. Discussions about a future catastrophic event, while often uncomfortable, can potentially prevent much pain and suffering. The use of prior directives regarding cardiopulmonary resuscitation and mechanical ventilation is appropriate in both instances.

Although economic considerations pervade many aspects of health care, caregivers should not allow the cost of treatment to dominate decisionmaking about withholding mechanical ventilation. On the other hand, the patient may factor into a prior directive the dire financial consequences that prolonged hospitalization might have on loved ones and refuse treatment on that basis.

There are many areas of potential conflict in decisions to withhold mechanical ventilation that require further clarification. Decisions about allocation of life-sustaining resources are implicitly made daily in medical practice. However, institutional policies that take into account both ethical and legal aspects of withholding therapy should be clarified and declared. Mechanisms for communication of advance directives among institutions, physicians, patients, and their families need to be developed.

Implementing the Decision To Withdraw Mechanical Ventilation

The decision to withdraw mechanical ventilation is usually made after a patient has received this and other treatment in an intensive care unit. Many individuals can be involved in the process, but a surrogate frequently makes the decision because the patient is incompetent or incapacitated. When it becomes clear to the health care team and family that mechanical ventilation is no longer benefiting or is excessively burdensome to the patient, a representative of the provider team, usually the attending physician or the responsible critical care unit physician, should meet with the patient and the family. The representative describes the options and the medical implications of continuing or withdrawing mechanical ventilation. The representative may give a medical recommendation, but the decision to withdraw or to continue resides with the patient if competent, or with a surrogate if the patient is incompetent or incapacitated. Living wills and durable power of attorney can greatly facilitate this decisionmaking process, but the steps are generally the same whether or not a prior directive exists. The following recommendations outline the decisionmaking process and its implementation.

It is the responsibility of the individual institution to assure the existence of written policies about withdrawing mechanical ventilation. These procedures must be consonant with appropriate ethical principles and with legal precedents that pertain to that locale. Important elements include:

1. Provision for continuing communication and consultation among all parties of interest. These include the patient, the family, physicians, nurses, respiratory therapists, social workers, and others.
2. These deliberations should result in a general agreement about withdrawing or continuing therapy. When they do not, some mechanism of resolution of conflict should exist. In some hospitals this may be a standing ethics committee. In other hospitals it could be an *ad hoc* committee. In many instances it is clergy known to the family. In a few instances, the courts have been involved in this decisionmaking process, although it is generally agreed that the courts are not well equipped to deal with this problem and their intervention should only be sought when an irreconcilable conflict arises.
3. When and if a consensus is reached that further ventilatory support is neither benefiting nor is desirable for the patient, the following events should occur.
4. A signed and witnessed note should be placed in the medical progress notes by the responsible physician that it is the patient's or the surrogate's decision that mechanical ventilation will be withdrawn. This documentation can briefly outline the events that led up to the decision, the patient's likely prognosis, and the parties to the decisionmaking process.
5. Once the documentation has occurred in the medical progress notes, an order can then be written to withdraw mechanical ventilation. This withdrawal procedure should provide for the patient's comfort and dignity. Although no details of a recommended withdrawal procedure are given here, in most cases the responsible physician should direct the procedure personally. Withdrawal procedures that result in great dyspnea or discomfort to the patient should be avoided, and the use of narcotics to blunt dyspnea and discomfort may be desirable.

Further Studies and New Directions

A diversity of further studies is needed. The medical literature is still imprecise about prognosis in many severe illnesses. More precise prediction of outcome is needed in both adult and pediatric illnesses that necessitate mechanical ventilation. Early predictors of the emergence of a persistent vegetative state would be useful. Subgroups of patients requiring mechanical ventilation who have a particularly high mortality rate or permanent loss of cognitive function (nearly 100 percent) need early identification.

There is a lack of study of the psychosocial implications of withholding and withdrawing mechanical ventilation. Very little is know about the perceptions of the healthy elderly and their desires regarding critical care and withdrawing and withholding mechanical ventilation. Most medical orders that withhold resuscitation or mechanical ventilation are ambiguous, and it is not clear to many physicians how to write a "do not resuscitate" order (13,14). Physicians perceive many problems when they withhold and withdraw mechanical ventilation. Their perceptions and fears are not well understood and only recently have studies begun to explore this area (15,16). While there are no ethical or legal differences between withholding or withdrawing mechanical ventilation, caregivers continue to be confused about the legal significance of withdrawal of therapy, and efforts should be undertaken to correct this misunderstanding (17).

In a practical manner it is difficult to communicate advance directives to emergency medical and intensive care unit personnel. Innovative devices and procedures are needed in this area. Few people know about living wills and durable power of attorney and how to implement them. Health care professionals should be encouraged to include information about prior directives with maintenance medical programs for chronically ill patients.

Careful collection of information about functional status and quality of life following weaning from mechanical ventilation would be useful since there is widespread fear that data about quality of life is currently being misinterpreted and inappropriately applied. With the extensive use of home ventilator therapy in this country, studies are needed of the psychosocial implications of long-term ventilation. There is little published information on the social adjustment of premature infants or adults who receive long-term mechanical ventilation. Reimbursement schemes for patients receiving mechanical ventilation at home are poorly developed. Some of this information will be difficult to obtain and much of it is subject to change as new technology and treatments are applied. However, taken as a whole, this body of information will help patients and caregivers make more informed decisions about life-sustaining treatments.

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Appendix F

The Effect of Normal Aging on the Assessment of Nutritional Status

Introduction

Dietary histories, anthropometric, biochemical, and hematologic measurements, and measurements of immune response are used to assess nutritional status in individuals of all ages. Changes in body composition and metabolism associated with normal aging affect many of the indices of nutritional status used in these assessment methods and may alter the nutritional standards needed to interpret findings for an individual patient. Some of these effects were discussed in chapter 8. Others are discussed below.

Dietary Histories

Dietary histories provide information about total caloric intake and fat, carbohydrate, protein, vitamin, and mineral components of the diet. The interpretation of this information requires a standard with which to compare findings for an individual patient. At present, no comprehensive standard for elderly patients is available.

In the absence of information about ideal dietary requirements for elderly people, the results of surveys of the actual dietary intake of healthy elderly individuals are sometimes used as a standard with which to compare dietary findings for an individual. The most comprehensive information about the nutritional status of healthy Americans was obtained from the Ten State Survey, conducted from 1968 to 1970 and the National Health and Nutrition Examination Surveys, conducted from 1971 to 1974 and from 1976 to 1980 (12).

There are several problems with the use of these survey findings as a nutritional standard, however. First, although the survey data provide information about actual average intake for healthy individuals over age 65, they may not accurately reflect average intake for subgroups of the elderly population, such as people with different ethnic and socioeconomic background than the surveyed population. Second, persons over 74 were not included in some surveys, and findings from other surveys were not broken down by age-defined subgroups of the elderly population (i.e. age 75 to 84 and 85+) (12,20). Finally, the use of findings based on the dietary intake of healthy elderly people as a standard for chronically or acutely ill elderly people may be inappropriate. Research on the dietary intake of older people in hospitals and nursing homes may provide a more appropriate basis for the development of nutritional standards for these populations (12).

Use of dietary histories for elderly people has been questioned because of the possibility that for some individuals declining memory may affect accurate recall. Dietary recall for the past 24 hours and prospective 1-week dietary histories have been shown to be relatively accurate in healthy older people who are living at home. Prospective 1-week dietary histories were found to be more accurate than retrospective reports of 24-hour food consumption for these individuals (14,18). For critically and terminally ill patients, accurate dietary histories may be more or less difficult to obtain depending on the patient's mental status and whether the caregivers have recorded food and fluid intake consistently.

Anthropometric Measurements

Measures of weight, lean body mass, and fat stores provide important information about nutritional status, but analysis of these measurements for elderly patients is complicated by changes in physiological characteristics and body composition associated with normal aging. Lean body mass decreases, resulting in an increase in the proportion of body weight as fat. In addition, a redistribution of fat occurs, particularly in females (12). Thus measurements that are abnormal for younger patients may be normal in elderly people.

Interpretation of anthropometric measurements is further complicated by the reduction in height that is associated with normal aging. Height is commonly used as a reference for other anthropometric measures, such as weight, but loss of height in elderly people, averaging 2.9 cm in men, and 4.9 cm in women, makes its use as a reference standard difficult. Moreover, accurate heights are often difficult to obtain in persons who are bedfast or confined to a wheelchair. Some experts have suggested the use of total arm length or knee to ankle measurements instead of height for elderly people because these characteristics are less affected by aging and easier to measure in a bed or chairfast patient (6,16). Assessment of height remains an important area of research in nutritional assessment of elderly people (12,17).

Accurate standards for weight in elderly people are also needed (7). The best weight-for-height information is that described by Master, et al. (15). This information was developed from a relatively small population of older, white Americans, however, and does not represent other ethnic and socioeconomic subgroups of the elderly population (12). New standards of ideal weight for height in elderly people have been proposed but remain controversial (1).

Weight loss as an indicator of malnutrition is discussed in chapter 8. Dramatic weight gain in elderly patients can also indicate disease-related nutrient deficiencies that are causing fluid retention (4).

As discussed in chapter 8, skinfold thickness is often used as a measure of fat stores. However, research indicates that alterations in fat distribution, altered skin turgor and elasticity, and other characteristic changes of the aging skin make skinfold measurements difficult to interpret after age 60. The tricep skinfold is used to estimate body composition, and, with a measure of midarm circumference, can be used to calculate midarm muscle circumference and midarm muscle area. Studies have confirmed the ability of midarm muscle area to predict lean body mass and formulas have been developed that allow the calculation of corrected arm muscle area for adults (3,10). Although standards for midarm muscle area have been reported for elderly subjects (9), they are limited by the fact that the oldest subject examined was age 75.

Creatinine excretion is another frequently used measure of lean body mass. Twenty-four-hour excretion of urinary creatinine varies directly with muscle mass of the body with reasonable accuracy. Creatinine excretion related to height has been used as an indicator of lean body mass in the diagnosis of nutritional deficiencies in hospitalized patients (2,19). The normal values for creatinine excretion were developed on the basis of a small sample of young adults, and there are no standards for elderly people. Moreover, some experts believe that creatinine excretion may be affected by age-related changes in renal function and that its usefulness in assessing nutritional status of older subjects may therefore be limited (12).

Biochemical Measurements

Serum albumin level is the most frequently used biochemical index of nutritional status, and low serum albumin levels often indicate poor nutritional status in patients of all ages. However, many factors alter the serum concentration. For example, marked reductions in serum albumin occur in kidney and liver disease, cancer, congestive heart failure, and other diseases that cause excessive urinary or gastrointestinal loss of protein. These conditions must be ruled out before malnutrition is diagnosed on the basis of low serum albumin concentration (8,12).

Most surveys show that the range of serum albumin levels in elderly people is broader than in younger people, but the majority still fall within the normal range. Significant reductions outside the lower limits of normal are rare in the healthy elderly. Thus, this measure is one of the most reliable indices of nutritional status in the elderly (5,12).

Serum transferrin is another biochemical index of nutritional status, but there are difficulties with its interpretation. Iron deficiency anemia increases transferrin concentration, whereas the anemia of infection and inflammatory diseases decreases transferrin concentration. Transferrin levels also vary inversely with tissue iron stores. Since iron stores are higher in the elderly than in younger subjects, their transferrin levels are lower. Thus, many apparently healthy elderly subjects have serum transferrin levels in the range usually described as deficient, not because of nutritional deficiencies but because of an increase in tissue iron stores. For this reason, serum transferrin levels for elderly patients must be interpreted with caution (12).

Other biochemical measurements, such as pre-albumin and retinol binding protein, have been suggested as protein status indicators, but these measurements have rarely been used in the elderly. Further work will be required to determine the importance of these measurements in detecting nutritional deficiencies in older people (12).

Hematologic Measurements

Low hemoglobin levels generally indicate poor nutritional status, but low hemoglobin levels are more common among healthy elderly people, particularly elderly men, than among younger individuals. The decrease in hemoglobin that occurs with aging is generally not due to the commonly recognized causes of anemia, such as iron deficiency, folate deficiency, or chronic disease, but instead is probably due to a reduction in the production of blood cells that may be related to normal aging. Thus, a mild decrease in hemoglobin levels may not indicate nutritional deficiency in elderly people. A severe decrease, however, usually does indicate a hematologic or nutritional abnormality that requires diagnosis and treatment (12,13)

Immunologic Assessment

Malnutrition causes changes in immune functioning of the individual, and tests of immune function are frequently used to assess nutritional status (11). Two commonly used tests of cell-mediated immunity are total lymphocyte count and delayed cutaneous hypersensitivity. While total lymphocyte count is not affected by normal aging, the proportion of certain types of lymphocytes is changed. Moreover, 50 percent of healthy persons over the age of 50 have impaired delayed cutaneous hypersensitivity (21). Since the changes in immune function that occur as a result of aging are almost identical to those caused by malnutrition, findings from immunologic measures for elderly patients must be interpreted with caution (8,12).

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Appendix G

Recommended Antibiotic Regimens for Elderly Patients With Selected Life-Threatening Infections

The following tables present recommended antibiotic regimens for elderly people with life-threatening bacterial pneumonias, urinary tract infections, infected decubitus ulcers, and septicemia associated with total parenteral nutrition (TPN), and estimates of the cost of the treatments. The tables were prepared for OTA by D.W. Bentley, W.H. Barker, K.M. Hunter, et al., University of Rochester, New York. The cost information is based on the cost of the antibiotics purchased from a Rochester hospital pharmacy and may not be representative of the cost of the same antibiotics nationwide.

Table G-1.—Recommended Antibiotic Regimens for Elderly Patients With Life-Threatening Bacterial Pneumonias

Setting	Usual pathogen(s)	Antibiotic(s)[a,b]	Maximum daily dose	Cost per day[c]	Minimum duration[d]	Cost per course
Community	*Streptococcus pneumoniae* Mixed flora *Hemophilus influenzae* Gram-negative bacilli	[3rd-generation cephalosporin[e]] or [chloramphenicol] plus aminoglycoside[f]	—[e] 4.0g —[f]	[$50.70-$168.12][e] or [$14.76] plus $13.40-$57.06[f]	7 days	$354.90-$1,176.84 or $103.32 plus $187.60-$399.42
Nursing home	Mixed flora *Streptococcus pneumoniae* Gram-negative bacilli	Antipseudomonal penicillins[g] or [3rd-generation cephalosporin[e]] or trimethoprim (TMP) sulfamethoxazole (SMX)[h] plus aminoglycoside[f]	—[g] —[e] TMP 1.2g SMX 6.0g —[f]	$76.57-$138.40[g] [$50.70-$168.12[e] or [$9.10] plus $13.40-$57.06[f]	14 days	$1,072-$1,937.60 or $709.80-$2,353.68 or $127.40 plus $315.00-$798.84
Hospital						
Not immunocompromised	Gram-negative bacilli *Staphylococcus aureus* *Streptococcus pneumoniae* Mixed flora	[3rd-generation cephalosporin[e]] plus aminoglycoside[f]	—[e] —[f]	[$50.70-$168.12[e] plus $13.40-$57.06[f]	14 days	$709.80-$2,353.68 plus $315.00-$798.84
Immunocompromised	As above plus *Legionella pneumophilia*	[3rd-generation cephalosporin[e]] plus aminoglycoside[f] plus [erythromycin] plus [TMP-SMX]	—[e] —[f] 4.0g TMP 1.2g SMX 6.0g	[$57.70-$168.12][e] plus $13.40-$57.06[f] plus [$39.16] plus [$9.10]	14 days	$709.80-$2,353.68 plus $315.00-$798.84 plus $548.24 plus $127.40

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[a] The antibiotic(s) listed first is (are) the drug(s) of choice.

[b] The first antibiotic listed within the brackets [] is an alternate choice for penicillin-allergic patients with a history of a delayed hypersensitivity type reaction. The second antibiotic listed within the brackets is an alternate choice for patients with a history of anaphylactic reaction or interstitial nephritis from either penicillin or cephalosporin.

[c] Total cost to patient is purchase cost plus 5 percent (inventory carrying cost) + $2.40 (dispensing fee).

[d] The recommended minimum duration (days) is an "average" duration for the empirically selected parenteral antibiotics only.

[e] Third-generation cephalosporins (maximum daily dose and cost per day) include cefotaxime (12 g, $127.44), cefoperazone (12 g, $134.10), moxalactam (12 g, $168.12), ceftizoxime (12 g, $134.22), ceftazidime (6 g, $78.80), and ceftraxone (2 g, $50.70).

[f] Aminoglycosides (maximum daily dose and cost per day) include amikacin (1.5 g, $57.06), gentamicin (5 mg/kg, $13.40), netilmicin (6.5 mg/kg, $24.02), and tobramycin (5 mg/kg, $32.01) (all based on 60 kg. patient).

[g] Antipseudomonal penicillins (maximum daily dose and cost per day) include carbenicillin (40 g, $76.57), ticarcillin (24-30 g, $87.92), pipracillin (24 g, $108.24), mezlocillin (24 g, $77.16), and azlocillin (24 g, $138.40).

[h] Not currently approved by the Food and Drug Administration for this indication.

SOURCES: **Usual pathogen and recommended antibiotics:** D.W. Bentley, "Bacterial Pneumonia in the Elderly: Clinical Features, Diagnosis, Etiology and Treatment," *Gerontology* 30:297, 1984; and C.J. Rozas and A.L. Goldman, "Responses to Bacterial Pneumonia," *Geriatrics* 37:61, 1982. **Maximum daily dose:** S.M. Norris, and G.L. Mandell, "Tables of Antimicrobial Agent Pharmacology," *Principles and Practices of Infectious Diseases*, G.L. Mandell, R.G. Douglas, Jr., and J.E. Bennett (eds.) (New York, NY: John Wiley & Sons, 1985). **Cost per day:** Strong Memorial Hospital Pharmacy, Rochester, NY. **Minimum duration:** D.W. Bentley, "Infectious Diseases," *Clinical Geriatrics*, I. Rossman (ed.) (Philadelphia, PA: J.B. Lippincott, 1986, in press).

Table G-2.—Recommended Empiric Antibiotic Regimens for Elderly Patients With Life-Threatening Urinary Tract Infections

Setting	Usual pathogen(s)	Antibiotic(s)[a b]	Maximum daily dose	Cost per day[c]	Minimum duration[d]	Cost per course
Community, nursing home, or hospital	*Escherichia coli*	Ampicillin or	12.0 g	$22.84 or	14 days	$319.76 or
	Klebsiella sp.	[vancomycin]	2.0 g	[$83.10]		$1,163.40
	Proteus sp.	plus		plus		plus
	Pseudomonas aeruginos[a]	aminoglycoside[e]	—[e]	$13.40-$57.06[e]		$315.00-$798.40
	Enterococcus	or		or		or
	Polymicrobial	antipseudomonas penicillins[f]	—[f]	$76.57-$138.40[f]		$1,072.00-$1,937.60
		or		or		or
		[3rd-generation cephalosporins][g]		$50.70-$168.12[g]		$709.80-$2,353.68

[a] The antibiotic(s) listed first is (are) the drug(s) of choice.

[b] The first antibiotic listed within the brackets [] is an alternate choice for penicillin-allergic patients with a history of a delayed hypersensitivity-type reaction. The second antibiotic listed within the brackets is an alternate choice for patients with a history of anaphylactic reaction or interstitial nephritis from either penicillin or cephalosporin.

[c] Total cost to patient is purchase cost plus 5 percent (inventory carrying cost) + $2.40 (dispensing fee).

[d] The recommended minimum duration (days) is an "average" duration for the empirically selected parenteral antibiotics only.

[e] Aminoglycosides (maximum daily dose and cost per day) include amikacin (1.5 g; $57.06), gentamicin (5 mg/kg; $13.40), netilmicin (6.5 mg/kg; $24.02), and tobramycin (5 mg/kg; $32.01) (all based on 60 kg. patient).

[f] Antipseudomonal penicillins (maximum daily dose and cost per day) include carbenicillin (40 g; $76.57), ticarcillin (24-30 g; $87.92), pipracillin (24 g; $108.24), mezlocillin (24 g; $77.16), and azlocillin (24 g; $138.40).

[g] Third-generation cephalosporins (maximum daily dose and cost per day) include cefotaxime (12 g; $127.44), cefoperazone (12 g; $134.10), moxalactam (12 g; $168.12), ceftizoxime (12 g; $134.22), ceftazidime (6 g; $78.80), and ceftraxone (2 g; $50.70).

SOURCES: **Usual pathogen and recommended antibiotics:** R. Gleckman, N. Blagg, D. Hibert, et al., "Community-Acquired Bacteremic Urosepsis in the Elderly Patients: A Prospective Study of 34 Consecutive Episodes, *Journal of Urology* 128:79, 1982; D. Kaye, "Urinary Tract Infections in the Elderly," *Bulletin of the New York Academy of Medicine* 56:209, 1980; A.R. Ronald, "Current Concepts in the Management of Urinary Tract Infections in Adults," *Medical Clinic of North America* 68:355, 1984; and E.T. Sherman, V. Tucci, L.S. Libow, et al., "Nosocomial Urinary Tract Infections in a Skilled Nursing Facility," *Journal of the American Geriatrics Society* 28:456, 1980. **Maximum daily dose:** S.M. Norris, and G.L. Mandell, "Tables of Antimicrobial Agent Pharmacology, *Principles and Practices of Infectious Diseases*, G.L. Mandell, R.G. Douglas, Jr., and J.E. Bennett (eds.) (New York, NY: John Wiley & Sons, 1985). **Minimum duration:** D.W. Bentley, "Infectious Diseases," *Clinical Geriatrics*, I. Rossman (ed.) (Philadelphia, PA: J.B. Lippincott, 1986, in press). **Cost per day:** Strong Memorial Hospital Pharmacy, Rochester, NY.

Table G-3.—Recommended Antibiotic Regimens for Elderly Patients With Life-Threatening Infected Decubitus Ulcers

Setting	Usual pathogen(s)	Antibiotic(s)[a b]	Maximum daily dose	Cost per day[c]	Minimum duration[d]	Cost per course
Community, nursing home, or hospital	*Proteus sp.*	[Clindamycin] or	4.8 g	[$120.32] or	14 days	$1,684.48 or
	Escherichia coli	[metronidazole] or	4.0 g	[$44.64] or		$624.96 or
	Pseudomonas aeruginosa	[chloramphenical]	—	[$14.76]		$206.64
	Staphylococcus aureus	plus		plus		plus
	Bacteroides fragilis	aminoglycoside[e]	—[e]	$13.40-$57.06[e]		$315.00-$798.84
	Polymicrobial	or		or		or
		antipseudomonal penicillins[f]	—[f]	$76.57-$138.40[f]		$1,072.00-$1,937.60
		or		or		or
		[3rd-generation cephalosporins][g]	—[g]	$50.70-$168.12[g]		$709.80-$2,353.68

[a] The antibiotic(s) listed first is (are) the drug(s) of choice.

[b] The first antibiotic listed within the brackets [] is an alternate choice for penicillin-allergic patients with a history of a delayed hypersensitivity-type reaction. The second antibiotic listed within the brackets is an alternate choice for patients with a history of anaphylactic reaction or interstitial nephritis from either penicillin or cephalosporin.

[c] Total cost to patient is purchase cost plus 5 percent (inventory carrying cost) + $2.40 (dispensing fee).

[d] The recommended minimum duration (days) is an "average" duration for the empirically selected parenteral antibiotics only.

[e] Aminoglycosides (maximum daily dose and cost per day) include amikacin (1.5 g; $57.06), gentamicin (5 mg/kg; $13.40), netilmicin (6.5 mg/kg; $24.02), and tobramycin (5 mg/kg; $32.01) (all based on 60 kg. patient).

[f] Antipseudomonal penicillins (maximum daily dose and cost per day) include carbenicillin (40 g; $76.57), ticarcillin (24-30 g; $87.92), pipracillin (24 g; $108.24), mezlocillin (24 g; $77.16), and azlocillin (24 g; $138.40).

[g] Third-generation cephalosporins (maximum daily dose and cost per day) include cefotaxime (12 g; $127.44), cefoperazone (12 g; $134.10), moxalactam (12 g; $168.12), ceftizoxime (12 g; $134.22), ceftazidime (6 g; $78.80), and ceftraxone (2 g; $50.70).

SOURCES: **Usual pathogen and recommended antibiotics:** A.W. Chow, and D.R. Burdge, "Pressure Sores," *Infections in the Elderly*, R.A. Gleckman and N.M. Gantz (eds.) (Boston, MA: Little Brown & Co., 1983), and D.W. Bentley, unpublished observations. **Maximum daily dose:** S.M. Norris, and G.L. Mandell, "Tables of Antimicrobial Agent Pharmacology, *Principles and Practices of Infectious Diseases*, G.L. Mandell, R.G. Douglas, Jr., and J.E. Bennett (eds.) (New York, NY: John Wiley & Sons, 1985). **Cost per day:** Strong Memorial Hospital Pharmacy, Rochester, NY. **Minimum duration:** D.W. Bentley, "Infectious Diseases," *Clinical Geriatrics*, I. Rossman (ed.) (Philadelphia, PA: J.B. Lippincott, 1986, in press).

Table G-4.—Recommended Antibiotic Regimens for Elderly Patients With Life-Threatening Total-Parenteral-Nutrition-Associated Septicemia

Setting	Usual pathogen(s)	Antibiotic(s)[a b]	Maximum daily dose	Cost per day[c]	Minimum duration[d]	Cost per course
Community or hospital	*Candida albicans* *Candida sp.* *Staphylococcus epidermidis* Gram-negative bacilli	Penicillinase-resistant penicillins[e] or [3rd-generation cephalosporin[f]] or [vancomycin] or amphotericin B	—[e] —[f] 2 g 1 mg/kg (60 kg)	$46.20-$74.76[e] or $50.70-$168.12[f] or $83.10 or $20.98	10 days	$460.20-$740.76 or $500.70-$1,680.12 or $830.10 or $209.80

[a] The antibiotic(s) listed first is (are) the drug(s) of choice.

[b] The first antibiotic listed within the brackets [] is an alternate choice for penicillin-allergic patients with a history of a delayed hypersensitivity-type reaction. The second antibiotic regimen listed within the brackets is an alternate choice for patients with a history of anaphylactic reaction or interstitial nephritis from either penicillin or cephalosporin.

[c] Total cost to patient is purchase cost plus 5 percent (inventory carrying cost) + $2.40 (dispensing fee).

[d] The recommended minimum duration (days) is an "average" duration for the empirically selected parenteral antibiotics only.

[e] Pennicillinase-resistant penicillins include methicillin (12 g; $74.76), oxacillin (12 g; $62.88), and nafcillin (9 g; $46.20).

[f] Third-generation cephalosporins (maximum daily dose and cost per day) include cefotaxime (12 g; $127.44), cefoperazone (12 g; $134.10), moxalactam (12 g; $168.12), ceftizoxime (12 g; $134.22), ceftazidime (6 g; $78.80), and ceftraxone (2 g; $50.70).

SOURCES: **Usual pathogen and recommended antibiotics:** D.W. Bentley, unpublished observations. **Maximum daily dose:** S.M. Norris, and G.L. Mandell, "Tables of Antimicrobial Agent Pharmacology," *Principles and Practices of Infectious Diseases*, G.L. Mandell, R.G. Douglas, Jr., and J.E. Bennett (eds.) (New York, NY: John Wiley & Sons, 1985). **Cost per day:** Strong Memorial Hospital Pharmacy, Rochester, NY. **Minimum duration:** D.W. Bentley, "Infectious Diseases," *Clinical Geriatrics*, I. Rossman (ed.) (Philadelphia, PA: J.B. Lippincott, 1986, in press).

Appendix H

Glossary of Acronyms and Terms

Glossary of Acronyms

AACN —American Association of Critical-Care Nurses
AARC —American Association for Respiratory Care
AARP —American Association of Retired Persons
ABC —Airway, Breathing, and Circulation; OR Assess, Breathe, and Circulate
ADAMHA —Alcohol, Drug Abuse, and Mental Health Administration (DHHS, PHS)
AGS —American Geriatrics Society
AHA —American Heart Association
AHA —American Hospital Association
ALS —advanced life support
ALS —amyotrophic lateral sclerosis
AMA —American Medical Association
AoA —Administration on Aging
APACHE —Acute Physiology and Chronic Health Evaluation
ASPEN —American Society for Parenteral and Enteral Nutrition
BLS —basic life support
CAPD —continuous ambulatory peritoneal dialysis
CAVH —continuous arteriovenous hemofiltration
CBO —Congressional Budget Office (U.S. Congress)
CCPD —continuous cycling peritoneal dialysis
CCRN —Critical Care Registered Nurse
CCU —coronary care unit
COBRA —Consolidated Omnibus Budget Reconciliation Act (of 1985)
COPD —chronic obstructive pulmonary disease
CPI —Consumer Price Index
CPR —cardiopulmonary resuscitation
CRNI —certified registered nurse, intravenous
CRT —cathode ray tube
CRTT —certified respiratory therapy technician
DHHS —U.S. Department of Health and Human Services
DME —durable medical equipment
DNI —Do-Not-Intubate order
DNR —Do-Not-Resuscitate order
DRG —diagnosis-related group
ECC —emergency cardiac care
ECMO —extracorporeal membrane oxygenation
EDTA —European Dialysis and Transplant Association
EKG —electrocardiogram (also ECG)
EMT —emergency medical technician
ESRD —end-stage renal disease
FDA —Food and Drug Administration (DHHS, PHS)
GAO —General Accounting Office (U.S. Congress)
GAU —geriatric assessment unit
GEC —Geriatric Education Center
GNP —gross national product
GRECC —Geriatric Research, Education, and Clinical Center
HCFA —Health Care Financing Administration (DHHS)
HFV —high-frequency ventilation
HMO —health maintenance organization
HRSA —Health Resources and Services Administration (DHHS, PHS)
ICD-9 —International Classification of Diseases, 9th edition
ICF —intermediate care facility
ICU —intensive care unit
IPD —intermittent peritoneal dialysis
IV —intravenous
JCAH —Joint Commission on the Accreditation of Hospitals
LVAD —left ventricular assist device
LVPPV —low-frequency, positive pressure ventilation
MMSE —Mini-Mental Status Exam
NCHS —National Center for Health Statistics (DHHS)
NCHSR/HTA —National Center for Health Services Research and Health Technology Assessment (DHHS, PHS)
NG —nasogastric (tube)
NHLBI —National Heart, Lung, and Blood Institute (DHHS, PHS, NIH)
NIA —National Institute on Aging (DHHS, PHS, NIH)
NIAID —National Institute of Allergy and Infectious Diseases (DHHS, PHS, NIH)
NIH —National Institutes of Health (DHHS, PHS)
NIMH —National Institute of Mental Health (DHHS, PHS, ADAMHA)
OCCPR —open-chest cardiopulmonary resuscitation
OHTA —Office of Health Technology Assessment (DHHS, PHS, NCHSR/HTA)

OTA —Office of Technology Assessment (U.S. Congress)
PHS —Public Health Service (DHHS)
PPS —prospective payment system (Medicare, Part A)
PRO —peer review organization
ProPAC —Prospective Payment Assessment Commission
QALY —quality adjusted life years
R&D —research and development
RDA —required daily allowance
RICU —respiratory intensive care unit
RN —registered nurse
RRT —registered respiratory therapist
SCO —supportive care only
SNF —skilled nursing facility
TPN —total parenteral nutrition
VA —Veterans' Administration
WAK —wearable artificial kidney

Glossary of Terms

Acute illness: An illness or condition characterized by sudden onset, marked symptoms, and short course. Compare *chronic illness*.

Advance directive: Instructions from a decisionally capable individual regarding decisions about future medical treatment in the event that he or she becomes decisionally incapable. An advance directive may specify medical treatment the individual consents to or refuses, designate a surrogate decisionmaker, or both. See also *durable power of attorney, living will*.

Advanced cardiac life support: Sophisticated procedures used to restore and/or maintain breathing and circulation in a person who has experienced cardiac and/or respiratory arrest. Procedures include the administration of drugs, electric shock, and intubation. Compare *basic life support*.

Allied health professionals: Health care personnel whose roles supplement those of physicians and nurses. Includes the many kinds of therapists and technicians trained in resuscitation, respiratory care, dialysis, nutrition, and intravenous therapy who have varying levels of responsibility for patient care and/or the medical equipment used in diagnosis and treatment.

Alzheimer's disease: The most common form of dementia, a chronic organic brain disease leading to severe, progressive loss of brain function and eventual death.

Amyotrophic lateral sclerosis (ALS): A motor neuron disease characterized by progressive weakening and wasting of the muscles that usually causes death within 2 to 5 years. Also called "Lou Gehrig's disease."

Anemia: A condition in which the blood is deficient in red blood cells, hemoglobin, or total volume. Associated with a lack of well-being in patients with chronic renal failure.

Antibiotic: Any one of many drugs that can inhibit or destroy microorganisms, and that is administered to cure or control numerous kinds of infections. See *life-sustaining antibiotic therapy*.

Arrhythmia: Any variation from normal, regular rhythm. Usually refers to abnormalities of cardiac rhythm, including ventricular fibrillation, tachycardia, and bradycardia.

Arteriovenous fistula: A surgically created connection between an artery and a vein, commonly used as part of the blood access system for hemodialysis.

Artificial airway: Surgically created route for passage of air into and out of the lungs.

Asystole: Absence of electrical activity in the heart.

Atherosclerosis: A common condition, in which deposits of fibrous and cellular tissue, cholesterol, and fat accumulate in the arteries, impeding blood flow.

Autonomy: Derived from the Greek "autos" (self) and "nomos" (rule, governance, or law), first used in reference to self-rule or self-governance in Greek city-states. In ethics, it is the principle that independent actions and choices of an individual should not be constrained by others.

Bacteremia: A pathological state characterized by the presence of bacteria in the blood.

Basic life support: The relatively simple resuscitative procedures used to restore and maintain breathing and circulation in a person who has experienced cardiac or respiratory arrest. Procedures include clearing the victim's airway, administering mouth-to-mouth resuscitation, and manually compressing the chest to stimulate the heart. Compare *advanced cardiac life support*.

Beneficence: Mercy, kindness, or charity to others. In ethics, it is the principle that one has a duty to convey benefits or to help others further their important and legitimate interests.

Best interest (standard): A legal standard to guide surrogate decisionmaking. By this standard, the surrogate makes the decision from the point of view of a hypothetical "reasonable person," on the basis of objective, socially shared criteria. Compare *substituted judgment*.

Biocompatible: Able to exist in harmony with living tissues, unlikely to cause infection, wear, or other deleterious effects.

Brain death: Irreversible cessation of all function of the entire brain, including the brainstem, as evidenced by loss of all reflexes and electrical activity. Since 1970, many States have enacted legislation recognizing brain death as a criterion for determining death.

Cardiac arrest: Cessation of the mechanical function of the heart, resulting in the loss of arterial blood pressure and irreversible brain damage and death if blood circulation is not restored within minutes.

Cardiopulmonary resuscitation (CPR): A range of technologies used to restore and maintain blood circulation and breathing in a person who has experienced cardiac and/or respiratory arrest. See *advanced cardiac life support, basic life support*.

Cardiovascular disease: Any of a diverse group of diseases characterized by the debilitation of the heart and/or blood vessels.

Caregivers: In this assessment, all persons who administer care to patients, i.e., health professionals including physicians, nurses, and allied health personnel; and lay persons, especially family members.

Case law: The aggregate of reported cases that form a body of jurisprudence, or the law of a particular subject as evidenced or formed by the decided cases, in distinction to statutes and other sources of law.

Catheter: A long, thin tube through which fluids may be introduced (e.g., nutritional formulas, drugs, blood) or drained (e.g., urine, blood) in the course of diagnosis or treatment.

Charge: The amount billed for products or services.

Chronic illness: An illness characterized by extended duration or frequent recurrence, and slow development. Chronic illnesses vary in severity and impact on a person's functional capacity. Some chronic illnesses are life-threatening and require continual medical treatment.

Chronic obstructive pulmonary disease (COPD): A diagnostic term that designates several diseases characterized by chronic airflow limitation: asthma, chronic bronchitis, emphysema, and less common diseases such as bronchiectasis and cystic fibrosis. COPD is a major cause of respiratory failure in elderly persons. Also called chronic obstructive lung disease.

Chronic renal failure: An irreversible condition in which the kidneys function at about one-quarter or less their normal level.

Chronological age: An individual's numerical age, dating from the time of his or her birth.

Code: Hospital terminology to designate the extent of resuscitative measures to be taken in the event of sudden cardiac arrest. See *Do-Not-Resuscitate*.

Code blue: A hospital's emergency call for professionals to respond to a patient in cardiac arrest.

Cognitive ability: The ability to comprehend, remember, reason, and judge information. In the context of this assessment, the content and the stability of cognitive ability are of major importance.

Cognitive impairment: Diminished *cognitive ability*.

Comorbidity: The simultaneous occurrence of multiple medical conditions or diseases in a single person.

Competent: In this assessment, any adult who has not been determined by a court to be incompetent, as there is legal presumption of competence. Compare *decisionally capable*.

Continuous ambulatory peritoneal dialysis (CAPD): A method of peritoneal dialysis that maximizes patient ambulation and self-care. CAPD is performed continuously, with exchange of dialysis fluid every 4 to 8 hours. CAPD is the most popular form of peritoneal dialysis and the most widely used form of home dialysis.

Continuous cycling peritoneal dialysis (CCPD): A recently developed form of peritoneal dialysis that combines nightly use of a machine to cycle the dialysate in and out of the peritoneal cavity (see *intermittent peritoneal dialysis*) and daytime use of ambulatory peritoneal dialysis (CAPD).

Cost: The actual amount spent to make facilities and services available and to provide them. Also see *charges* and *payment*. "Cost" is also used in a generic sense when the distinction between cost, charges, and payments is not clear.

Critically ill: In this assessment, a patient who is experiencing an acute life-threatening episode or who is believed to be in imminent danger of such an episode. A critically ill patient is medically unstable and, if not treated, likely to decline.

Decisionally capable: A patient who is assessed, without the involvement of a court, to possess the mental ability to make decisions or to participate in decisionmaking. Compare *competent*.

Decisionally incapable: A patient who is assessed, usually without the involvement of a court, to lack the mental capacity to make a particular decision. Compare *incompetent*.

Decubitus ulcers: Lesions or cavities on the skin frequently caused by lying in bed for a long period of time. Also called bed sores or pressure sores.

Defibrillator: An electrical device used to terminate atrial or ventricular fibrillation. High-voltage electrical shock is delivered to the heart through two paddles placed on the patient's chest.

Dementia: Severe impairment of mental function and global cognitive abilities of long duration (months to years) in an alert individual. Some forms (especially *Alzheimer's disease*) are permanent; others are reversible.

Diabetes mellitus: A chronic disease characterized by inadequate secretion or utilization of insulin, by elevated blood sugar or the presence of sugar in the urine, by thirst, hunger, and weight loss. Long-term complications include disorders of the kidney, circulatory system, and retina.

Diagnosis-related groups (DRGs): Diagnostic categories used by Medicare (Part A) as case-mix measures, under the prospective hospital payment system. Categories are drawn from the International Classification of Diseases and modified by the presence of a surgical procedure, patient age, comorbidities or complications, and other criteria.

Dialysate: The fluid into which impurities removed from the blood by dialysis are passed. Also called "dialysis fluid."

Dialysis: In general, any process in which components of a liquid or solution are separated on the basis of the selective movement of different kinds of molecules through a semipermeable membrane. In renal dialysis, impurities are separated and removed from the blood. The two main types of renal dialysis are *hemodialysis* and *peritoneal dialysis*.

Dialyzer: A machine for performing hemodialysis. It consists of a compartment for the blood, a compartment for the dialysate, and a semipermeable membrane separating the two.

Distributive justice: Theories and principles for the fair allocation of resources in general and scarce resources in particular. See *justice*.

Do-Not-Intubate (DNI) order: A directive by a physician not to intubate a patient for mechanical ventilation. Other life-sustaining efforts short of intubation are not ruled out.

Do-Not-Resuscitate (DNR) order: A directive by a physician to withhold cardiopulmonary resuscitation in the event that a patient experiences cardiac or respiratory arrest. Also called "no code."

Durable power of attorney: A legal instrument empowering a designated person to act on another's behalf. Unlike the traditional power of attorney, the "durable" power does not lapse if the person who executed it becomes decisionally incapable. Originally intended to permit financial or property transactions, durable powers of attorney are also used to delegate medical decisionmaking authority.

Elderly population: In this assessment, all persons who are age 65 and over.

Electrocardiogram (ECG or EKG): A graphic record of the electrical activity of the heart as detected by an electrocardiograph machine.

Endotracheal tube: A tube designed to be inserted through the natural opening of a patient's trachea (windpipe), usually for mechanical ventilation. The two types of endotracheal tubes are nasotracheal tubes (inserted through the trachea via the patient's nose) and orotracheal tubes (inserted via the patient's mouth).

End-stage renal disease (ESRD): A late stage of chronic renal failure in which kidney function is less than 10 percent of normal, and regular dialysis or kidney transplantation is required to maintain life.

Enteral nutrition: The infusion of nutrients into a person's stomach or intestine via tubes placed through the nose or a surgical opening into the gastrointestinal tract. (Though the term is sometimes defined to include oral nutrition supplements, in this assessment it refers only to tube feeding.) Compare *parenteral nutrition*.

Ethics committee: Consultative committee in a hospital or other institution whose role is to analyze ethical dilemmas and to advise and educate health care providers, patients, and families regarding difficult treatment decisions.

Euthanasia: An act intended to cause the merciful death of a person who is suffering from what is believed to be an incurable condition.

Extubation: Removal for any reason from a patient of a nasogastric, tracheostomy, or other tube used in treatment.

Family consent laws: Laws that empower a family member to take over decisionmaking for a decisionally incapable patient without going through guardianship proceedings.

Gastrostomy tube: An enteral feeding tube inserted through the patient's abdomen into the stomach.

Geriatrician: A physician who possesses special knowledge of geriatrics or geriatric medicine. See *geriatrics*.

Geriatrics: The medical knowledge of physical disability in older persons—including the prevention, diagnosis, and treatment of disorders. Also called "geriatric medicine."

Gerontology: The study of aging in all its aspects, including biological, psychological, sociological, economic, and historical perspectives.

Glomerulonephritis: Acute or chronic inflammation of the kidneys characterized by inflammation of the capillary loops in the glomeruli. A serious risk for chronic renal failure.

Guardian: A person appointed by a court to protect the interests of a person who is decisionally incapable.

Hemodialysis: The oldest and most widely used form of renal dialysis. Blood is pumped in a continuous extracorporeal loop, from an artery, through a *dialyzer*, and back through a vein. Treatments are typically three times weekly, with each session lasting 3 to 5 hours.

Hemofiltration: An extracorporeal process of filtering the blood to correct various imbalances.

Hospice: A method of care that provides supportive medical and social services for dying individuals and their families. Hospice services can be provided in the patient's home, a nursing home, hospital, a special hospice facility, or a combination of these.

Hydration: The addition of water, as by intravenous fluids, to the body.

Hypercapnia: Elevated concentration of carbon dioxide in the blood. Also called "hypercarbia."

Hypertension: A common and significant cardiovascular disorder characterized by persistently high arterial blood pressure. Important risk factor for life-threatening conditions, including cardiac arrest, stroke, and chronic renal failure.

Hypoxia: Deficiency of oxygen in the tissues.

Iatrogenic: Complication, injury, or unfavorable result that is due to medical care. Especially drug reactions and hospital-acquired infections. Compare *nosocomial*.

Incidence: The number of new occurrences of a disease in a specified population and period of time. Incidence is often expressed as a rate (e.g., the number of new cases of pneumonia per 1,000 nursing home residents during a 12-month period). Compare *prevalence*.

Incompetent: A person who has been determined by a court of law to be unable to make and articulate rational decisions.

Infection: An illness caused by an organism such as a bacterium, virus, or fungus.

Informed consent: A legal term that refers to a person's consent to a proposed medical intervention after being provided information deemed relevant to that decision. The information that is legally required include: diagnosis, nature and purpose of proposed intervention, risks and consequences of proposed treatment, probability that the treatment will be successful, feasible treatment alternatives, and prognosis if the treatment is not given.

Intensive care unit (ICU): A special hospital unit for complex treatment and continuous monitoring of critically ill patients.

Intermittent peritoneal dialysis: A form of peritoneal dialysis that involves the use of a machine to pump sterile dialysate into a patient's peritoneal cavity and to remove the spent dialysate. Typically performed for 10 to 12 hours, 3 nights per week.

Intravenous: Through a vein. Intravenous procedures are commonly used for nutritional support, and for administration of antibiotics and other drugs.

Intravenous feeding: Nutritional support provided through a vein. See *parenteral nutrition*.

Intubation: Insertion of a tube into a body canal or hollow organ, e.g., insertion of an endotracheal tube into the trachea for mechanical ventilation.

Justice: Generally refers to fair and equal treatment. In ethics, it is the principle that one should act in such a manner that no one person or group bears a disproportionate share of benefits or burdens. See *distributive justice*.

Kidney failure: See *renal failure*.

Life-sustaining antibiotic therapy: The use of any antibiotic against a life-threatening infection. Not a particular drug or family of drugs.

Life-sustaining technologies: Drugs, medical devices, or procedures that can keep individuals alive who would otherwise die within a foreseeable, though usually uncertain, time.

Living will: A document in which a decisionally capable person expresses in advance his or her wish not to receive certain life-sustaining treatments in the event that he or she becomes decisionally incapable in the future.

Maintenance dialysis: Hemodialysis or periotoneal dialysis that is required indefinitely or until renal transplantation. Also called "chronic dialysis."

Mechanical ventilation: The use of a machine to take over the role of a patient's respiratory muscles, inducing rhythmic inflation and emptying of the lungs, to permit adequate transport of oxygenation and ventilation. See *ventilator*.

Medicaid: A joint Federal/State program that provides medical benefits for certain low-income persons. Medicaid eligibility, coverage, and reimbursement regulations are determined by each State within Federal guidelines and vary significantly among States.

Medicare: A nationwide, federally administered health insurance program that pays for medical care for elderly and disabled beneficiaries and persons with end-stage renal disease. Part A (Hospital Insurance) covers hospital care, some posthospital nursing home care, and some home health care services. Part B (Supplementary Medical Insurance) covers physician services, hospital outpatient services, outpatient physical therapy and speech pathology services, and various other limited ambulatory services and supplies such as durable medical equipment. Part B also covers home health services for Medicare beneficiaries who have Part B coverage only.

Morbidity: Ill health. Within a population, the number of sick persons or cases of disease in a specified time period.

Myocardial infarction: Damage to a portion of the myocardium (heart muscle) as a result of insufficient blood to the heart. Commonly called "heart attack."

Nasogastric (NG) tube: An enteral feeding tube inserted through a patient's nose, down the esophagus, and into a patient's stomach.

Natural death acts: State statutes that authorize living wills.

Negative pressure ventilator: A device that induces breathing by the application of negative (i.e., below atmospheric) pressure. These relatively simple devices are effective for some medically stable patients with paralysis of the respiratory muscles. The iron lung is a well-known early example.

Nonmaleficence: Generally associated with the maxim "primum non nocere" (above all, do no harm). In ethics, it is the principle that one has a duty not to inflict evil, harm, or risk of harm.

Nosocomial: An infection or disease acquired in a hospital or other health care facility.

Nutritional support: Artificial methods of providing nourishment and fluids. See *enteral nutrition*, *parenteral nutrition*.

(DRG) Outlier: An atypical case that has an extremely long length of hospital stay or extraordinarily high costs when compared to most discharges classified in the same diagnosis-related group.

Oxygenation: The delivery of oxygen to the blood.

(Cardiac) Pacemaker: A device that substitutes for the heart's natural ability to regulate heartbeat, by generating electrical pulses to the heart. May be implanted within the chest wall or applied externally. Also called "pacer."

Palliative care: Care intended to keep a patient comfortable, but not intended to prolong life.

Parens patriae: A legal term that refers to the sovereign power of guardianship over persons who are disabled, such as minors, insane, or incompetent persons. Grants courts authority to appoint a guardian.

Parenteral nutrition: Refers to any form of nutrition that does not utilize the gastrointestinal tract but usually refers to the infusion of nutrients directly into the bloodstream via catheter. One form of parenteral nutrition is total parenteral nutrition. Compare *enteral nutrition*.

Payment: The dollar amount actually paid for a product or service. Also called "expenditure."

Peritoneal dialysis: One of two major forms of renal dialysis. Dialysis occurs inside the patient's peritoneum. See *intermittent peritoneal dialysis*, *continuous ambulatory peritoneal dialysis*, and *continuous cycling peritoneal dialysis*.

Peritoneum: The semipermeable membrane lining the abdominal cavity. In peritoneal dialysis, this is the membrane through which impurities are passed from the blood into the dialysate.

Peritonitis: Inflammation of the peritoneum. Peritonitis is the single most important complication of peritoneal dialysis.

Pneumonia: An acute or chronic inflammation of lungs, caused by exposure to a wide variety of microbial pathogens or to toxic substances. Pneumonia is one of the five leading causes of death in the elderly population.

Polypharmacy: The concurrent use of multiple medications by one patient.

Positive pressure ventilator: A ventilator that delivers respiratory gas to a patient by the application of positive (i.e., above atmospheric) pressure to the patient's airway.

Prevalence: In epidemiology, the number of existing cases of a disease present during a particular time period and in relation to the size of the population. Often expressed as a rate, e.g., the prevalence of diabetes per 1,000 persons per year. Compare *incidence*.

Prognosis: An informed judgment about the likely course and probable outcome of a disease based on knowledge of the facts of a particular case.

Prospective payment: A method of payment for medical care in which the amount of payment is set prior to the delivery of services. The basis for Medicare Part A (hospital) payment since 1983. Compare *retrospective cost-based reimbursement*.

Renal: Pertaining to the kidneys.

Renal dialysis: See *dialysis*.

Renal failure: Acute or chronic loss of renal function to a level that is incompatible with life. Also called "kidney failure." See *chronic renal failure*.

Respect for persons: In ethics, the principle that individuals should be treated as ends in themselves and never merely as means to the ends or goals of others.

Respirator: See *ventilator*.

Respiratory arrest: Complete cessation of effective breathing.

Respiratory failure: Life-threatening condition in which the respiratory system does not provide adequate oxygenation and/or ventilation.

Respiratory insufficiency: Acute or chronic, life-affecting (in children, growth-affecting) disorder in *oxygenation* and/or *ventilation*.

Respiratory intensive care unit (RICU): A specialized unit in an acute care hospital for critically ill patients requiring mechanical ventilation and continuous monitoring of respiration.

Resuscitation: Procedures for the restoration of heart rhythm and maintenance of blood flow and breathing following cardiac or respiratory arrest. See also *advanced cardiac life support* and *basic life support*.

Resuscitation policies: Guidelines adopted by some hospitals, nursing homes, and other institutions to govern decisions about the use of resuscitation.

Retrospective cost-based reimbursement: A method of payment for health care services in which the amount of payment to a health care provider or patient is based on the costs that were already incurred in providing the services. Compare *prospec-*

tive payment.

Severely debilitated: In this assessment, a patient who has serious or multiple impairments or comorbidities, with severely compromised functional capacity and physiological reserve. A severely debilitated person is medically stable but highly vulnerable to new physiological stress.

Substituted judgment (standard): A legal standard for surrogate decisionmaking. By this standard, the surrogate makes the decision on the basis of what is known about the patient's personal values and preferences. Compare *best interest.*

Surrogate decisionmaker: A person who is designated to make decisions on behalf of a person who is incapable of making decisions. A surrogate decisionmaker may be selected in advance of a person's becoming decisionally incapable by means of a durable power of attorney or living will or may be selected after a patient has become decisionally incapable.

Terminally ill: A person for whom a prognosis of death has been made, based on diagnosis of an illness that has a predictably fatal progression that cannot be stopped by any known treatment.

Time-limited trial: Clinical trial of a treatment for a pre-determined time period.

Total parenteral nutrition (TPN): An intravenous feeding technique that is capable of supplying sufficient nutrients to maintain a person's normal weight and growth over a prolonged period.

Tracheostomy: An artificial opening in a patient's trachea, which is created by cutting through the patient's neck into the trachea, often for the purpose of inserting a tube for mechanical ventilation.

Tube feeding: See *enteral nutrition.*

Uremia: A symptom complex that accompanies ESRD, characterized by retention in the blood of excessive byproducts of protein metabolism.

Urinary tract infection: Any infection of one or more parts of the urinary tract.

Ventilation: The removal of carbon dioxide from the blood.

Ventilator: A medical device that assists or replaces the natural mechanisms for breathing. The terms ventilator and respirator are used interchangeably, but ventilator is currently the preferred term.

Ventilator-dependent: A patient who must rely on a ventilator for survival, whether for a short time, intermittently but frequently, or constantly.

Ventricular fibrillation: Twitching or beating of the ventricles of the heart in an uncoordinated pattern, without effective contraction and cardiac output. The form of arrhythmia that most frequently precedes cardiac arrest.

Weaning: The step-by-step process of decreasing a patient's dependence on mechanical ventilation until the patient's ability to breathe independently is fully restored and the ventilator can be removed.

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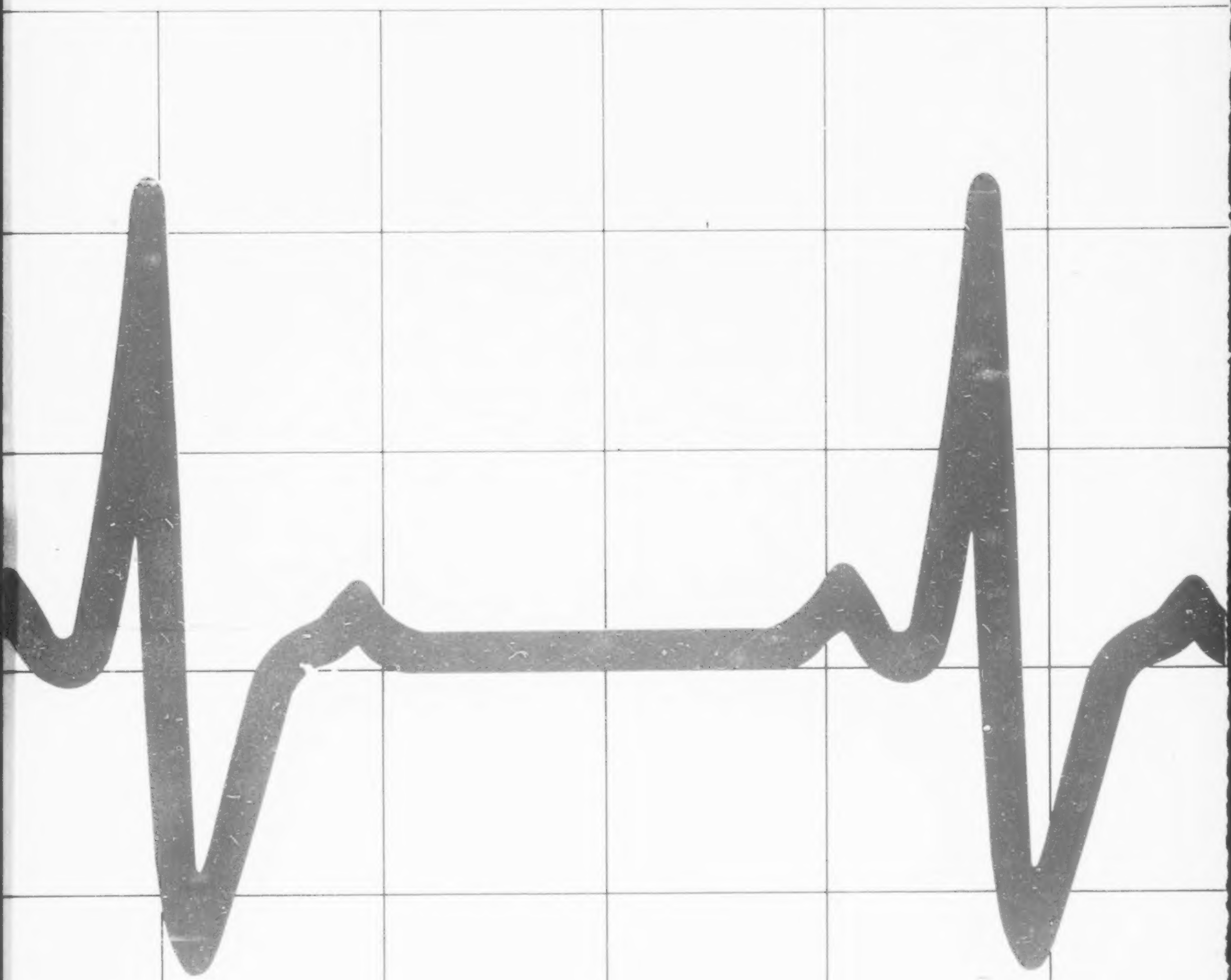

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